

# **Exhibit 2**

## **(Filed Under Seal)**

**Dr. Russell L. Lamb**  
**President**  
Monument Economics Group, LLC  
1530 Wilson Boulevard  
Suite 560  
Arlington, VA 22209

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## **I. Introduction and Summary of Conclusions**

### ***A. Expert Background and Qualifications***

1. I am the President and Co-Founder of Monument Economics Group (“Monument”), an economic consulting firm based in Arlington, Virginia. Monument provides economic research and quantitative and statistical analyses to clients in the United States, Canada and elsewhere internationally.
2. I have studied the economics of markets and prices for more than 25 years and have consulted on these issues for more than 20 years. I graduated from the University of Tennessee, Knoxville in 1987 (summa cum laude, Phi Beta Kappa) as the top graduate in my class in the College of Arts and Sciences. I earned a Master’s degree in economics from the University of Maryland in 1989. I received the Doctor of Philosophy degree in economics from the University of Pennsylvania in 1994. My economic research has been published in peer-reviewed journals such as *Journal of Econometrics*, *Journal of Development Economics*, *CATO Journal*, *Regulation*, and others. I have also served as a referee for leading economics journals, including the *International Economic Review*, *Journal of Business and Economic Statistics*, *Journal of Labor Economics*, *American Journal of Agricultural Economics*, and *Contemporary Economic Policy*.
3. Prior to co-founding Monument, I was a Senior Vice President at Nathan Associates from January 2013 until September 2016, where I directed the firm’s Litigation line of business. I have held a variety of positions as an economist in government, academia, and other consulting firms. From 1994 until 1999 I was an Economist (later Senior Economist) with the Federal Reserve System of the United States in Washington, D.C. and Kansas City, MO where I analyzed prices and markets for economic policymakers. From 1999 until 2004 I taught economics at North Carolina State University in Raleigh, NC. I have been hired as an economic consultant to the World Bank and the Government of Peru, as well as assisting on a wide range of economic consulting projects for private firms, government agencies, and law firms in a variety of contexts. I have previously been retained by counsel to calculate economic damages arising from mass tort and antitrust litigation. Courts in the United States and Canada have relied upon my economic analyses of the market in certifying classes of

both Direct Purchasers and Indirect Purchasers in litigation involving allegations of anticompetitive conduct; for example, in *Jabo's Pharmacy, Inc., et al., v. King Pharmaceuticals, Inc., In re: Puerto Rican Cabotage Antitrust Litigation, In re: Aftermarket Auto Lighting Products Antitrust Litigation, In re: Titanium Dioxide Antitrust Litigation, In re: Polyurethane Foam Antitrust Litigation, Eugene Allan, et al., v. Realcomp II, Ltd., et al., Fond du Lac Bumper Exchange, et al., v. Jui Li Enterprise Company Ltd., et al.*, and the Canadian LCD litigation<sup>1</sup>. In addition to my consulting activities, I continue to teach Law and Economics at The George Washington University, where I am an adjunct faculty member in the Department of Economics. A copy of my complete curriculum vitae is attached as Appendix A to this Expert Report. Monument is being compensated for my work in this matter at my usual and customary rate of \$650 per hour. Monument's compensation in this matter is not contingent upon the content of my testimony or the outcome of this litigation.

#### *B. Summary of Plaintiffs' Allegations*

4. I understand that an Amended Class Action Complaint was filed on October 13, 2015 by J M Smith Corporation (doing business as Smith Drug Company) and Rochester Drug Co-Operative, Inc.<sup>2</sup> ("Plaintiffs") against Defendants Actavis, PLC ("Actavis"), Forest Laboratories, LLC ("Forest"), Merz GMBH & Co. KGAA, Merz Pharma GMBH & Co. KGAA and Merz Pharmaceuticals GMBH (collectively "Merz") (Actavis, Forest, and Merz collectively, "Defendants").<sup>3</sup> I understand that the Plaintiffs allege that the relevant market is the market for memantine hydrochloride - including Namenda IR,

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<sup>1</sup> The Canadian LCD litigation is formally: The Fanshawe College of Applied Arts and Technology and LG Philips LCD Co., Ltd, L.G. Philips LCD America, Inc., Samsung Electronics Co. Ltd., Samsung Electronics Canada Inc., Hitachi Ltd., Hitachi Displays, Ltd., Hitachi Canada, Ltd., Hitachi Electronics Devices (USA) Inc., Sharp Corporation, Sharp Electronics Corporation, Sharp Electronics of Canada Ltd., Toshiba Corporation, Toshiba Matsushita Display Technology Co. Ltd., Toshiba America Corporation, Toshiba of Canada Limited, AU Optronics Corporation America, Chi Mei Optoelectronics USA, Inc. Chi Mei Optoelectronics Japan Co. Ltd. And Chunghwa Picture Tubes, Ltd.

<sup>2</sup> I understand Rochester Drug Co-Operative filed separately, but the October 13, 2015 complaint is the operative complaint for both.

<sup>3</sup> In the United States District Court for the Southern District of New York, J M Smith Corporation d/b/a, Smith Drug Company v. Actavis, PLC, Forest Laboratories, LLC, Merz GmbH & Co. KGAA, Merz Pharma GmbH & Co. KGAA and Merz Pharmaceuticals GmbH, Civil Action No. 15-cv-7488, First Amended Class Action Complaint, October 13, 2015 (hereafter "Complaint") at ¶¶1, 193.

Namenda XR, and AB-rated generic memantine hydrochloride (“generic Namenda IR”) - in the United States and its territories.<sup>4</sup>

5. I understand that Plaintiffs’ allegations in this matter relate to Defendants’ engagement in a two-part, allegedly anticompetitive and “unlawful scheme to maintain a monopoly and to allocate the United States market for branded and generic versions of memantine hydrochloride.”<sup>5</sup> Specifically, I understand that Plaintiffs allege that Forest first entered into an unlawful “pay-for-delay” or “reverse payment” settlement with Mylan Pharmaceuticals, Inc. and settled with other generic competitors in 2009-2010 to delay generic competition for Namenda IR until January (then July) 2015, in order to: (1) artificially extend the time during which Defendants could charge supracompetitive, monopoly prices for Namenda IR; and also (2) buy time to plan, announce and implement a “hard switch” or “product hop” from its branded Namenda IR product to Namenda XR, a switch designed to undermine and impair generic competition when it belatedly began.

6. I understand from Counsel for Plaintiffs that Plaintiffs are bringing this case on behalf of themselves and the following proposed Class:

All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, and/or generic Namenda IR 5 or 10 mg tablets (including an authorized generic), and/or branded Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, and/or from any generic manufacturer at any time during the period from June 2012 until September 30, 2015 (the “Class”).

7. Based on my understanding of Plaintiffs’ allegations in this matter and instructions from Counsel for the Plaintiffs, the materials, documents and data I have reviewed to date, and my training and experience in economics, econometrics and statistics, I have analyzed two but-for scenarios that Plaintiffs allege would have occurred in a world free of the Defendants’ alleged misconduct:

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<sup>4</sup> Complaint at ¶¶202-231.

<sup>5</sup> Complaint at ¶1.



8. Under the first scenario, I assume that, had the Defendants not entered into an allegedly illegal agreement with Mylan, they still would have settled, but without a large reverse payment and with an entry date on November 2, 2012 (rather than in 2015 as provided for in their allegedly unlawful agreement). In analyzing this scenario, I have relied on an analysis I understand was conducted by Professor Einer Elhauge in which he determines that a payment-free settlement would have provided for an entry date of November 2, 2012. Mylan would have entered then and, Plaintiffs allege, other generic competitors would have as well under the terms of their agreements with Forest. I understand that Plaintiffs allege that absent a settlement, Mylan would have prevailed in the patent litigation brought against it, resulting in generic entry by it in June 2012, and by other generic competitors under the terms of their agreements with Forest. For the purposes of calculating damages arising under this scenario (the “No Reverse-Payment But-For World”), I have assumed a generic entry date of June 2012, or November 2, 2012. I have also relied upon what I understand to be Professor Elhauge’s opinion that, as a matter of economics, had AB-rated generics become available starting on June 2012 (or in the alternative November 2, 2012), Defendant Forest would have begun marketing Namenda XR one year prior to the date of generic entry.

9. Under the second scenario, I have been instructed to analyze the case in which Defendants did not engage in their “Hard Switch” strategy and no generic entry occurred prior to the actual date at which AB-rated generics for Namenda IR became available (i.e. July 2015). In this scenario, I have been asked to consider damages suffered by direct purchasers of Namenda XR arising solely from Defendant Forest’s announcement of a “Hard Switch” from Namenda IR to Namenda XR (the “No Hard Switch But-For World”). I analyze the effect of this conduct below.

### *C. Assignment*

10. I have been asked by Counsel for Plaintiffs to analyze the following questions:

- a. Whether prices paid by proposed Class members for memantine hydrochloride were impacted by the delay of generic entry that Plaintiffs allege arose from Defendants’ allegedly illegal agreement with Mylan;

- b. Whether prices paid by proposed Class members for memantine hydrochloride were impacted by Defendants' unlawful "Hard Switch" strategy;
- c. Whether it is possible to establish, using economic analyses and evidence common to the proposed Class as a whole, rather than specific to individual members, that proposed Class members were injured by the Defendants' alleged anticompetitive conduct under two separate but-for worlds: 1) the No Reverse-Payment But-For World, assuming that generic entry was delayed and would have occurred earlier otherwise; and 2) the No Hard Switch But-For World, assuming that generic entry would have occurred in July 2015 just as it did; and
- d. The amount of aggregate damages suffered by proposed Class members as a result of the alleged misconduct under two separate but-for worlds: 1) the No Reverse-Payment But-For World, assuming that generic entry was delayed and would have occurred earlier otherwise; and 2) the No Hard Switch But-For World, assuming that generic entry would have occurred in July 2015 just as it did.

11. For the purposes of analyzing these issues, I have assumed that Defendants have in fact engaged in the anticompetitive practices Plaintiffs allege. I have not, however, assumed that Defendants' alleged misconduct resulted in anticompetitive injury, or that all members of the proposed Class were injured as a result of the alleged misconduct. Rather, the analysis of those issues is the focus of my Expert Report.

*D. Materials Reviewed*

12. In performing my analyses, I have undertaken economic research to understand the market for memantine hydrochloride and the prices paid for memantine hydrochloride products by members of the proposed Class. Specifically, I have conducted economic analyses of prices for memantine hydrochloride products using the data on brand-name

and generic drugs available from IMS Health, Inc. (“IMS”)<sup>6</sup> as well as the transaction-level data produced by Forest and generic manufacturers Amneal, Dr. Reddy’s, Lupin, Mylan, Teva, and Wockhardt.<sup>7</sup> I have also reviewed documents produced by the various parties in this matter (including documents, expert reports and testimony from the previous action brought by the New York Attorney General - the “NYAG” action), documents or filings presented before the U.S. Food and Drug Administration (“FDA”), as well as a variety of publicly-available documents including trade press and academic literature. A complete list of the materials I have considered in reaching my opinions is contained in Appendix B.

#### *E. Conclusions*

13. Based on my analyses and research into the market for memantine hydrochloride, as well as my training and experience in economics, I have reached the following conclusions:

- a. All or nearly all proposed Class members were impacted by Defendants’ allegedly anticompetitive agreement with Mylan, assuming that generic entry was delayed and would have occurred earlier otherwise, in that they paid higher prices for brand-name Namenda IR, Namenda XR, and/or generic memantine hydrochloride than they otherwise would have had generic competition started sooner, because they would have purchased (or purchased more) generic memantine hydrochloride at prices below branded Namenda and would have purchased the generic at lower prices.
- b. All or nearly all proposed Class members who purchased at least Namenda IR and XR, or XR, were impacted by Defendants’ anticompetitive Hard Switch strategy in that they paid higher prices for Namenda XR than they otherwise would have for generic memantine

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<sup>6</sup> IMS provides market data tracking sales of prescription drugs measured in dollars and units. IMS Institute for Healthcare Informatics, “HSRN Data Brief: National Sales Perspectives,” IMS Health, 2011 (hereafter, “National Sales Perspectives Brief”).

<sup>7</sup> I also received aggregated data for Sun and Macleods. However, for the reasons discussed below I was ultimately unable to use these data in my damages analysis.

hydrochloride, and they would have purchased the less expensive generic (or more of it) in place of the more expensive branded Namenda.

- c. I have calculated aggregate, class-wide damages arising from Defendants' alleged misconduct under two separate but-for worlds: 1) the No Reverse-Payment But-For World with generic entry occurring either June 2012 or November 2, 2012; and 2) the No Hard Switch But-For World. Total damages suffered by proposed Class members are between \$6.09 billion and \$6.93 billion under the No Reverse-Payment But-For World, and between \$776 million and \$814 million under the No Hard Switch But-For World.

## II. Industry Background

### A. Regulatory Requirements for New Drugs

14. The FDA is responsible for the approval of branded, generic and over-the-counter drugs sold in the United States. Before marketing a new drug (also known as an “innovator drug”), a brand-name drug manufacturer must obtain approval from the FDA by filing a New Drug Application (“NDA”).<sup>8</sup> The NDA approval process allows the FDA to evaluate “[w]hether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.”<sup>9</sup> Patent information is also submitted at the time the NDA is submitted.<sup>10</sup> Once the drug is approved by the FDA, the NDA filer receives authorization to market it in the United States.<sup>11</sup> The FDA also lists patents that cover the drug in a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the “Orange Book.”<sup>12</sup>

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<sup>8</sup> FDA, New Drug Application (NDA) Introduction, updated March 29, 2016 (hereafter “FDA NDA”). Available at

<https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/newdrugapplicationnda/default.htm>.

<sup>9</sup> FDA NDA.

<sup>10</sup> FDA, Frequently Asked Questions on Patents and Exclusivity, updated December 5, 2016. Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm>.

<sup>11</sup> FDA, Frequently Asked Questions about the FDA Drug Approval Process, updated February 7, 2017. Available at <https://www.fda.gov/drugs/resourcesforyou/specialfeatures/ucm279676.htm>.

<sup>12</sup> The Orange Book is also available on the Internet at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

15. According to the FDA, “[a] generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use.”<sup>13</sup> Under the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the “Hatch Waxman Act”), a generic manufacturer seeking approval to market a generic drug product is required to submit data to the FDA demonstrating that the generic product is bioequivalent<sup>14</sup> to the innovator drug product.<sup>15</sup> If the FDA determines that the generic drug is bioequivalent to the innovator drug product, it assigns the generic drug an “AB” rating.<sup>16</sup>

16. I understand that an AB-rating allows pharmacists to substitute the generic drug product for the brand-name drug.<sup>17</sup> I also understand that state laws allow (and in some cases require) the pharmacist to fill out a prescription with an AB-rated generic drug even in cases where the doctor has written a prescription for a brand name drug.<sup>18</sup> According to a study published by the Congressional Budget Office (“CBO”), by 1984 all states had automatic drug-product substitution laws.<sup>19</sup> According to a consumer information website published by the Federal Trade Commission (“FTC”), “[e]ach state has a law allowing pharmacists to substitute generic drugs for many brand-name products if your doctor doesn’t specify that the brand-name drug is required.”<sup>20</sup> As a result, most of the brand-name drug market is susceptible to competitive and/or required substitution of AB-rated generics for brand-name pharmaceuticals by pharmacists.

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<sup>13</sup> FDA, Abbreviated New Drug Application (ANDA): Generics, updated September 6, 2017 (hereafter “FDA ANDA”). Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm>.

<sup>14</sup> The FDA defines “bioequivalent” drugs as pharmaceutical equivalents whose rate and extent of absorption are not statistically different from the innovator drug when administered to patients or subjects at the same molar dose under similar experimental conditions. See FDA, “Nomenclature (as excerpted from the Orange Book).” Available at [https://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4137B1\\_07\\_Nomenclature.pdf](https://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4137B1_07_Nomenclature.pdf).

<sup>15</sup> FDA ANDA.

<sup>16</sup> Orange Book 2017 at p. xiii-xiv.

<sup>17</sup> FRX-AT-01750245-48 at 46.

<sup>18</sup> Complaint at ¶46; “How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” Congressional Budget Office, July 1998, (hereafter, “CBO Study”) at p. 7.

<sup>19</sup> Also, “[b]y 1989, the dispensing of generic drugs on ‘brand-written’ prescriptions rather than generically written prescriptions had become the chief source of generic drug sales through pharmacies.” CBO Study at p.7.

<sup>20</sup> FTC Consumer Information, Generic Drugs and Low-Cost Prescriptions, July 2012. Available at <http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions#getting>.

17. In addition, managed care entities, such as Prescription Benefit Managers (“PBMs”), also employ mechanisms to promote generic substitution, including formulary management and pricing contracts with pharmacies providing financial incentives for generic substitution. For example, according to one CBO report, “[a]nother important way that PBMs lower drug costs is by promoting generic substitution, not just through formularies but also through their pricing contracts with pharmacies [...] PBMs’ contracts sometimes provide financial incentives that make generic substitution even more profitable for pharmacists.”<sup>21</sup> In general, “[t]hose consumers who are more sensitive to price, or who are covered by health plans that encourage generic substitution, are more likely to buy a generic drug when it becomes available.”<sup>22</sup> Thus, substitution of AB-rated generic equivalents for brand-name pharmaceuticals is an important feature of the market which can lead to dramatically lower prices for the same treatment.

18. Under the Hatch-Waxman Act, a generic manufacturer seeking approval to sell a generic version of a brand name drug is allowed to file an Abbreviated New Drug Application (“ANDA”):

The object of the ANDA process is to demonstrate that the generic drug product has the same active ingredient, route of administration, dosage form and strength, and proposed labeling as the brand-name drug. The ANDA also must contain sufficient information to demonstrate that the generic drug is “bioequivalent” to the relevant brand-name product.<sup>23</sup>

An ANDA allows a generic manufacturer “to rely on the FDA’s previous findings of safety and effectiveness for the referenced brand-name drug, and thus the applicant does not have to provide its own clinical studies to demonstrate the generic drug product’s safety and effectiveness.”<sup>24</sup> As a result, generic manufacturers can realize significant development cost savings and generic drugs may become available in the marketplace more rapidly.

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<sup>21</sup> CBO Study at p. 8.

<sup>22</sup> CBO Study at p. 29.

<sup>23</sup> Federal Trade Commission, “Generic Drug Entry Prior to Patent Expiration: An FTC Study,” July 2002, (hereafter, “FTC Study”) at p. 5.

<sup>24</sup> FTC Study at p. 5.

19. An ANDA must also contain a certification regarding each patent listed in the Orange Book related to the relevant NDA.<sup>25</sup> A Paragraph IV certification under the Hatch Waxman Act asserts that the relevant patent or patents are invalid or non-infringed by the generic applicant.<sup>26</sup> After filing a Paragraph IV certification, the generic applicant is required to notify the patent holder and the NDA filer.<sup>27</sup> After receiving notice of a Paragraph IV certification, the patent holder has 45 days to file a patent infringement suit against the ANDA applicant<sup>28</sup> in order to trigger an automatic stay of FDA approval of the ANDA until the earliest of: (a) the expiration of 30 months from the receipt of notice of the paragraph IV certification; (b) the date of the patent's expiration; or (c) a final determination by a court that the patent is invalid or non-infringed.<sup>29</sup>

20. Under the Hatch Waxman Act, the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible for an exclusivity period during which no other generic manufacturer can market the generic version of the brand-name drug.<sup>30</sup> Since 2003, the first generic manufacturer to file an ANDA with a Paragraph IV certification is entitled to 180-marketing exclusivity, and when more than one generic applicant files ANDAs on the same day, they are each entitled to shared exclusivity.<sup>31</sup>

### *B. Competitive Effects of Generic Entry*

21. The extensive regulations guarding new drug development mean that branded manufacturers expend significant resources on researching, developing, and testing new drug formulations. To help incentivize branded pharmaceutical manufacturers to

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<sup>25</sup> “The statute provides ANDA applicants with four certification options: they may certify (I) that the required patent information has not been filed; (II) that the patent has expired; (III) that the patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (IV) that the patent is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval.” FTC Study at pp. 5-6.

<sup>26</sup> FDA, Center for Drug Evaluation and Research (“CDER”), “Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act,” June 1998 at p. 2. Available at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079342.pdf>.

<sup>27</sup> FTC Study at pp. 6-7.

<sup>28</sup> “If the patent holder does not bring suit within 45 days, the FDA approval process may proceed, and the FDA may approve an ANDA as soon as regulatory requirements are fulfilled.” FTC Study at p. 7.

<sup>29</sup> FTC Study at p. 7.

<sup>30</sup> FTC Study at p. 7.

<sup>31</sup> FDA, Center for Drug Evaluation and Research (“CDER”), “Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day,” July 2003. Available at <https://www.fda.gov/downloads/drugs/guidances/ucm072851.pdf>.



continue these investments, new product developers are granted patents protecting their compound or manufacturing process. Further, in recognition of the substantial amount of patent life manufacturers spend bringing their product to market, the FDA also has the ability to grant patent extensions. While encouraging new drug development, patent protection also provides branded manufacturers with considerable market power. This market power is only temporary, however, and ends with the expiration of the manufacturer's patent. The expiration of patent exclusivity removes the barriers to entry previously protecting branded manufacturers from competition.

22. As discussed above, generic pharmaceuticals that meet FDA standards for bioequivalence offer the same efficacy as the branded version of the drug. That is, in granting a generic the AB or bioequivalence rating, the FDA effectively signals to physicians, pharmacists, and patients that the product will have the exact same effect and will work just as well as the brand. Generic manufacturers, all offering the same product (and the same as the brand), compete vigorously on price. The lower prices and increased competition introduced by generic entry are well-established in economic research. As explained in one publication, “[p]harmaceutical industry studies indicate that the first generic competitor enters the market at a price that averages approximately 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.”<sup>32</sup>

23. In contrast to the temporary legal monopoly granted to branded manufacturers during the applicable patent life, generic entry has been shown to create significant competition and drive prices down towards marginal costs. As I discuss below, this price-based competition creates powerful incentives for branded manufacturers to take steps to attempt to delay generic entry.

### *C. The Pharmaceutical Supply Chain*

24. The pharmaceutical supply chain is comprised of drug manufacturers (either brand-name or generic), wholesalers, pharmacies, end consumers and third-party payers.

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<sup>32</sup> Organisation for Economic Co-operation and Development, Directorate for Financial and Enterprise Affairs, Competition Committee, “Generic Pharmaceuticals,” DAF/COMP/WD(2014)51, June 19, 2014 at p. 2.



Manufacturers of prescription drugs sell directly to drug wholesalers, and in some circumstances, they also sell directly to retail pharmacy chains, mail order and specialty pharmacies, hospital chains, and health plans.<sup>33</sup> Pharmaceutical manufacturers determine the Wholesale Acquisition Cost (“WAC”), which is typically the “baseline price at which wholesale distributors purchase products.”<sup>34</sup>

25. Drug wholesalers purchase prescription drugs from manufacturers and distribute them to retail pharmacies, mail-order pharmacies, hospitals, long-term care and other medical facilities. In turn, retail pharmacies purchase prescription drugs from wholesalers, and in some cases directly from the manufacturers, and ultimately distribute those drugs to their customers holding prescriptions. PBMs process prescriptions for the groups that pay for drugs, usually insurance companies or corporations.<sup>35</sup>

26. The pharmaceutical supply chain moves drugs, including branded Namenda IR, Namenda XR, and generic Namenda IR, from manufacturers to patients through a straightforward set of links. Choice of pharmaceutical therapy rests with patients and their healthcare providers, especially doctors. Patient demand for pharmaceuticals translates into demand at the pharmacy level, and, in some cases, through long-term care facilities and hospitals. Patients may purchase pharmaceuticals from retail pharmacies or mail-order pharmacies. Manufacturers typically sell branded pharmaceuticals directly to wholesalers and, in smaller volumes, to long-term care facilities. Wholesalers, in turn, sell to pharmacies and other intermediaries. Demand for Namenda IR, Namenda XR and generic Namenda IR by direct purchasers who are proposed Class members here reflects the need to fill patient prescriptions. Thus, while switching occurs either at the patient level or at the pharmacy, this is ultimately reflected in the volumes and market share of Namenda IR, Namenda XR, and generic Namenda IR purchased by proposed Class members.

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<sup>33</sup> “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain,” Prepared for the Kaiser Family Foundation by: The Health Strategies Consultancy LLC, March 2005 (hereafter, “Follow the Pill”) at p. 4.

<sup>34</sup> Follow the Pill at p. 17.

<sup>35</sup> “PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including the use of formularies and cost sharing.” Follow the Pill at p. 2.

### III. The Memantine Hydrochloride Market

#### A. *Namenda*

27. Namenda is Defendant Forest's brand-name version of memantine hydrochloride, a drug used in the treatment of Alzheimer's disease.<sup>36</sup> Namenda is an N-methyl-D-aspartate ("NMDA") receptor antagonist, which "works to prevent the overstimulation by glutamate, an amino acid that excites the nerves, and in excess, is a powerful nerve-cell killer."<sup>37</sup> Namenda is the only NMDA receptor antagonist approved for use by the FDA in patients with moderate to severe Alzheimer's disease.<sup>38</sup> Namenda is currently available in the U.S. in two forms, a twice-daily immediate-release tablet ("Namenda IR") and a once-daily extended-release tablet ("Namenda XR"). Table 1 below shows sales in dollars of Namenda IR, Namenda XR, and generic memantine hydrochloride products in the U.S. from January 2011 to June 2017 based on IMS National Sales Perspective ("NSP") data.<sup>39</sup>

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<sup>36</sup> Complaint at ¶1. See also, FDA, Center for Drug Evaluation and Research, "Approval Package For: Application Number 21-487, Approval Letter(s)," October 16, 2003 (hereafter "Namenda Approval Letter") at p. 1. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2003/21-487\\_Namenda\\_Approv.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-487_Namenda_Approv.pdf).

<sup>37</sup> Complaint at ¶90. See also, FRX-AT-01726785-792 at 786.

<sup>38</sup> See, for example, National Institute on Aging, "How is Alzheimer's Disease Treated?" updated August 2, 2017 (hereafter "2017 National Institute on Aging"). Available at <https://www.nia.nih.gov/health/how-alzheimers-disease-treated>; FRX-AT-03835462-5510 at 5464; Complaint at ¶90.

<sup>39</sup> The IMS National Sales Perspectives data, which will be discussed in more detail below, measures sales at actual transaction prices and "monitors every major class of trade and channel of distribution for prescription pharmaceuticals, over-the-counter products and select, self-administered diagnostic products in the United States, measuring volume of dollars and units moving from manufacturers into various outlets within all 50 states." National Sales Perspectives Brief.

**Table 1**  
**NSP Annual Sales of Namenda and Generic Namenda IR (USD)**  
**(January 2011 through June 2017)**

Year	Namenda IR	Namenda XR	Generic Namenda IR	Total
2011	\$1,456,126,668			\$1,456,126,668
2012	\$1,619,995,800			\$1,619,995,800
2013	\$1,786,771,621	\$71,460,815		\$1,858,232,436
2014	\$1,526,538,135	\$605,051,639		\$2,131,589,774
2015	\$687,625,045	\$1,006,955,660	\$27,572,900	\$1,722,153,605
2016	\$23,772,490	\$1,074,286,613	\$42,540,523	\$1,140,599,626
2017	\$4,913,529	\$465,173,239	\$16,337,714	\$486,424,482
<b>Total</b>	<b>\$7,105,743,288</b>	<b>\$3,222,927,966</b>	<b>\$86,451,137</b>	<b>\$10,415,122,391</b>

Source: NSP data.

### *B. Summary of Events*

28. The following section summarizes the attempts of generic manufacturers to enter the memantine hydrochloride market and the actions taken by Defendants to delay generic entry to prevent or forestall the loss of sales and profits on the Namenda franchise that would have accompanied it. A full account of the background as alleged by Plaintiffs can be found in Plaintiffs' First Amended Complaint at paragraphs 90 to 192.

#### *i. Memantine Hydrochloride Patent*

29. U.S. Patent No. 5,061,703 ("703 Patent"), which is owned by Defendant Merz and was originally obtained on October 29, 1991, covers the use of memantine hydrochloride in treating Alzheimer's disease.<sup>40</sup> On June 28, 2000, Defendants Forest and Merz entered into a licensing agreement regarding the development of memantine hydrochloride for use in treating Alzheimer's disease.<sup>41</sup> This agreement provided Forest with the exclusive right to market a memantine hydrochloride product in the U.S. under the 703 Patent.<sup>42</sup> Forest submitted a New Drug Application ("NDA") to the FDA on December 19, 2002 seeking approval to market 5mg, 10mg, 15mg, and 20mg memantine

<sup>40</sup> Complaint at ¶¶2, 95; Joachim Bormann, Markus R. Gold and Wolfgang Schatton, Inventors; Merz + Co. GmbH & Co, Assignee, Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia. U.S. Patent 5,061,703, October 29, 1991.

<sup>41</sup> Complaint at ¶93; Forest Laboratories Inc., SEC Form 8-K EX-99.1, period ending December 2, 2013 (hereafter "Forest 8-K Ex. 99.1") at p. 59.

<sup>42</sup> Complaint at ¶93; Forest 8-K Ex. 99.1 at p. 59.

hydrochloride tablets (under the brand name Namenda).<sup>43</sup> On October 16, 2003, the FDA approved Forest's NDA for Namenda IR tablets. Forest announced the launch of Namenda IR shortly after on January 13, 2004.<sup>44</sup>

30. The 703 Patent had an original expiration date of April 11, 2010.<sup>45</sup> However, in March 2009, the U.S. Patent and Trademark Office ("PTO") granted Forest a five-year extension on the patent for time spent obtaining FDA approval (the maximum amount of time allowed under the Hatch-Waxman Act), delaying the expiration date to April 11, 2015.<sup>46</sup> Further, on June 18, 2014, the FDA granted Forest a six-month period of regulatory exclusivity (which expired on October 11, 2015) for testing its Namenda IR tablets on the pediatric population.<sup>47</sup>

ii. Lawsuits Filed Against Generic Manufacturers by Forest and Merz

31. Starting in late 2007, several generic manufacturers filed ANDAs with the FDA seeking to market generic forms of Forest's Namenda IR tablets prior to the expiration of the 703 Patent, claiming that the 703 Patent was invalid or that the proposed generics would not infringe upon the 703 Patent (or both) (i.e., paragraph IV certifications).<sup>48</sup> These generic manufacturers began sending paragraph IV certification notices to Forest in October 2007. Specifically,

- Barr Pharmaceuticals ("Barr") sent notice to Forest on December 7, 2007.<sup>49</sup>
- Teva Pharmaceutical Industries ("Teva") sent notice to Forest on November 29, 2007.<sup>50</sup>
- Cobalt Laboratories ("Cobalt") sent notice to Forest on December 5, 2007.<sup>51</sup>

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<sup>43</sup> Namenda Approval Letter at p. 1.

<sup>44</sup> Namenda Approval Letter at p. 1; FRX-AT-04568337-345 at 337; FRX-AT-03496434-449 at 447; Complaint at ¶¶96-97.

<sup>45</sup> FRX-AT-03496434-449 at 447; Complaint at ¶95.

<sup>46</sup> FRX-AT-04369603-613 at 603; Complaint at ¶99.

<sup>47</sup> Forest Laboratories, Inc., "Forest Obtains Six Months U.S. Pediatric Exclusivity for NAMENDA® and NAMENDA XR®," *BusinessWire*, June 18, 2014. Available at <http://www.businesswire.com/news/home/20140618005438/en/Forest-Obtains-Months-U.S.-Pediatric-Exclusivity-NAMENDA%C2%AE>; Complaint at ¶2.

<sup>48</sup> FRX-AT-03490463; Complaint at ¶102.

<sup>49</sup> FRX-AT-04312274-281.

<sup>50</sup> FRX-AT-03487982-999.

<sup>51</sup> FRX-AT-03624221-254.

- Orchid Chemicals & Pharmaceuticals (“Orchid”) sent notice to Forest on December 7, 2007.<sup>52</sup>
- Lupin Ltd. (“Lupin”) sent notice to Forest on December 13, 2007.<sup>53</sup>
- Upsher-Smith Laboratories (“Upsher-Smith”) sent notice to Forest on December 12, 2007.<sup>54</sup>
- Wockhardt Ltd. (“Wockhardt”) sent notice to Forest on December 14, 2007.<sup>55</sup>
- Genpharm Inc. (“Genpharm”) sent notice to Forest on December 17, 2007.<sup>56</sup>
- Mylan Pharmaceuticals Inc. (“Mylan”) sent notice to Forest on December 17, 2007.<sup>57</sup>
- Interpharm Inc. (“Interpharm”) sent notice to Forest on December 18, 2007.<sup>58</sup>
- SUN INDIA Pharmaceutical Industries (“Sun”) sent notice to Forest on December 20, 2007.<sup>59</sup>
- Dr. Reddy’s Laboratories Inc. (“Dr. Reddy’s”) sent notice to Forest on January 2, 2008.<sup>60</sup>

32. In January 2008, Defendants Forest and Merz filed lawsuits against generic manufacturers Barr, Cobalt, Lupin, Orchid, Teva, Upsher-Smith, and Wockhardt, alleging infringement of the 703 Patent. Under Hatch-Waxman, the filing of the patent infringement suits automatically triggered a 30-month period during which the FDA was unable to approve ANDAs filed by any of these generic manufacturers.<sup>61</sup> Defendants

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<sup>52</sup> FRX-AT-03169232-273.

<sup>53</sup> FRX-AT-03490110-131.

<sup>54</sup> FRX-AT-04536177-6202.

<sup>55</sup> FRX-AT-03490173-0243.

<sup>56</sup> FRX-AT-03169392-9423.

<sup>57</sup> FRX-AT-03169424-455.

<sup>58</sup> FRX-AT-03169456-478.

<sup>59</sup> FRX-AT-04599903-917.

<sup>60</sup> FRX-AT-04544984-45011.

<sup>61</sup> Complaint at ¶104; United States District Court of Delaware, *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD., Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH, v. Cobalt Laboratories Inc., Lupin Pharmaceuticals, Inc., Lupin Ltd., Orchid Pharmaceuticals Inc., Orchid Chemicals & Pharmaceuticals Ltd. (d/b/a Orchid Healthcare), Teva Pharmaceuticals USA, Inc., Upsher-Smith Laboratories, Inc., Wockhardt USA Inc., and Wockhardt Limited*, Complaint, filed January 10, 2008; United States District Court of Delaware, *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD.,*

Forest and Merz also filed similar lawsuits against Dr. Reddy's, Genpharm, Interpharm, Mylan, Sun, and others in January 2008, automatically triggering a 30-month period during which the FDA was unable to approve ANDAs filed by these additional generic manufacturers.<sup>62</sup> I understand that Barr, Teva, Cobalt, Amneal (which was substituted for Interpharm), Upsher-Smith, Lupin, Mylan, Sun, Orchid, Dr. Reddy's, and Wockhardt were "all first to file substantially complete ANDAs with Paragraph IV certifications to the '703 Patent. As a result, each would be entitled to 180-days of shared marketing exclusivity for generic Namenda, and any one of them could trigger the running of the 180-day exclusivity period by either launching a product or obtaining a judgment of invalidity or non-infringement of the '703 Patent."<sup>63</sup>

iii. Contingent Entry Agreements between Defendants Forest and Merz and Certain Generic Manufacturers

33. Following the filing of the 703 Patent infringement lawsuits, but prior to the scheduled trials, I understand that Defendants Forest and Merz settled their pending patent litigation with a number of the generic manufacturers.<sup>64</sup> I understand Plaintiffs allege that in "connection with these settlements, Forest entered into licensing agreements with Teva (including Barr, which had become a subsidiary of Teva), Amneal, Dr. Reddy's, Lupin, Sun, Upsher-Smith, Cobalt (later acquired by Watson Pharmaceuticals Inc., which was later acquired by Actavis, which is now operating as Allergan), Mylan, Orchid, and Wockhardt, whereby Forest provided to each of them the assurance and protection that if it agreed to delay entering the market until January 11, 2015, none of its generic competitors would come to market earlier and enjoy first-filer sales while the

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*Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH, Plaintiffs, v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.*, Complaint, filed January 10, 2008.

<sup>62</sup> Complaint at ¶105; United States District Court of Delaware, *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD., Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH, v. Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, Genpharm Inc., Genpharm, L.P., Interpharm Holdings, Inc., Interpharm Inc., Mylan Pharmaceuticals Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Kendle International Inc., and Sun India Pharmaceutical Industries Limited (a/k/a Sun Pharmaceuticals Industries Limited)*, Complaint, filed January 25, 2008.

<sup>63</sup> Complaint at ¶106.

<sup>64</sup> In particular, I understand that Defendants Forest and Merz settled with the following generic manufacturers in the following months: Cobalt – July 2009; Teva – July 2009; Upsher-Smith – September 2009; Wockhardt – September 2009; Amneal – September 2009; Apotex Corp. – September 2009; Sun – October 2009; Lupin – December 2009; Dr. Reddy's – December 2009; Orchid – April 2010; Mylan – July 2010; and other generic manufacturers that filed ANDAs. See Complaint at ¶113.

settling generic remained on the sidelines.”<sup>65</sup> I further understand that Plaintiffs allege that each of these Contingent Entry Agreements included a provision that extended the agreed-to generic launch date from January 11, 2015 to July 11, 2015 in the event that Forest was ultimately granted an additional pediatric exclusivity period of six months.<sup>66</sup> Final FDA approval was granted for the marketing of generic versions of Namenda IR as follows:

- Dr. Reddy’s: April 14, 2010.<sup>67</sup>
- Sun: May 5, 2010.<sup>68</sup>
- Teva: October 25, 2011.<sup>69</sup>
- Orchid: March 12, 2012.<sup>70</sup>
- Amneal: April 10, 2015.<sup>71</sup>
- Lupin: April 10, 2015.<sup>72</sup>
- Mylan: January 30, 2015.<sup>73</sup>

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<sup>65</sup> Complaint at ¶114. See also, Shannon Henson, “Upsher-Smith, Others Exit Namenda Patent Case,” *Law360*, September 14, 2009; Melissa Lipman, “Lupin Gets Namenda License In Forest Settlement,” *Law360*, December 22, 2009; “Orchid Chem settles litigation with Forest Labs,” *Reuters*, April 29, 2010; Ben James, “Forest, Merz, Wrap Up Namenda Patent Litigation,” *Law360*, July 22, 2010. I further understand that Plaintiffs allege that around the same time these Contingent Entry Agreements were entered into, Defendants Forest and Merz settled their above-reference 703 Patent lawsuits with all remaining potential first-filing generic manufacturers. See Complaint at ¶115.

<sup>66</sup> Complaint at ¶116.

<sup>67</sup> FDA, “ANDA 090048 Approval Letter,” April 14, 2010. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2010/090048s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/090048s000ltr.pdf); Complaint at ¶133.

<sup>68</sup> Drugs@FDA, “ANDA 090058.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090058>; Complaint at ¶133.

<sup>69</sup> Drugs@FDA, “ANDA 090052.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090052>; Complaint at ¶133.

<sup>70</sup> FDA, “ANDA 090044 Approval Letter,” March 12, 2012. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2012/090044Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/090044Orig1s000ltr.pdf); Complaint at ¶133.

<sup>71</sup> Drugs@FDA, “ANDA 090041.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090041>; Complaint at ¶133.

<sup>72</sup> FDA, “ANDA 090051 Approval Letter,” April 10, 2015. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2015/090051Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/090051Orig1s000ltr.pdf); Complaint at ¶133.

<sup>73</sup> Mylan received tentative approval on April 2, 2010. MYLMEGA\_000023 – 26; Drugs@FDA, “ANDA 079225.” Available at



- Upsher-Smith: July 31, 2015.<sup>74</sup>

iv. Launch of Namenda XR

34. I understand that on August 21, 2009, “Forest submitted an NDA seeking to market Namenda XR, a once-daily, extended release reformulation of Namenda.”<sup>75</sup> This NDA was approved by the FDA on June 21, 2010.<sup>76</sup> Three years later, on June 13, 2013, Forest announced that Namenda XR was now available throughout the U.S.<sup>77</sup>

35. According to Plaintiffs’ allegations, Forest began to consider a plan to convert all patients from Namenda IR to Namenda XR as early as Fall 2012.<sup>78</sup> In 2013, around the time Namenda XR was launched, I understand that Forest ceased actively marketing Namenda IR and began expending significant resources on a new campaign directed at maximizing conversion from Namenda IR to Namenda XR.<sup>79</sup> On October 18, 2013, Forest executives announced the decision to discontinue Namenda IR in an internal email: “Forest has made the decision to discontinue sales of Namenda IR and transition all patients to Namenda XR.”<sup>80</sup>

36. I understand Plaintiffs allege that Forest began to consider an option in which it would discontinue or dramatically restrict the supply of Namenda IR several months before the availability of generic memantine hydrochloride in order to accomplish a “forced switch” or “Hard Switch” whereby physicians and patients would have little

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<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=079225>; Complaint at ¶133.

<sup>74</sup> Upsher-Smith received tentative approval on April 15, 2010. Drugs@FDA, “ANDA 090043.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090043>; FDA, “ANDA 090043 Approval Letter,” July 31, 2015. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2015/090043Orig1s000Ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/090043Orig1s000Ltr.pdf); Complaint at ¶133.

<sup>75</sup> FRX-AT-00348814-16; Complaint at ¶145.

<sup>76</sup> FDA, Center for Drug Evaluation and Research, “Approval Package For: Application Number 22-525, Approval Letter(s),” June 21, 2010. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022525Orig1s000Approv.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022525Orig1s000Approv.pdf); Complaint at ¶145.

<sup>77</sup> Forest Laboratories, Inc., “Forest Announces U.S. Availability of New Once-Daily NAMENDA XR,” *BusinessWire*, June 13, 2013. Available at <http://www.businesswire.com/news/home/20130613005088/en/Forest-Announces-U.S.-Availability-New-Once-Daily-NAMENDA>; Complaint at ¶149.

<sup>78</sup> FRX-AT-01775240-41 at 40; Complaint at ¶¶153, 164.

<sup>79</sup> A December 2013 Forest Presentation titled “Namenda Transition” estimates total direct marketing expenses of \$371 million in 2013. See FRX-AT-01670083 at slide 3.

<sup>80</sup> FRX-AT-01779417-19 at 17.



choice but to switch to Namenda XR because Namenda IR would no longer be available (and generic versions of branded Namenda IR would not be AB-rated to, and so not substitutable for, branded Namenda XR).<sup>81</sup> I discuss a number of internal Forest documents confirming this strategy below.

37. I understand that, “[b]etween February and June 2014, Forest regularly emphasized publicly its intent to discontinue Namenda IR on August 15, 2014.”<sup>82</sup> On February 14, 2014, Forest issued a press release announcing that it planned to discontinue sales of its Namenda IR tablets as of August 15, 2014, noting further that Namenda solution and Namenda XR would still be available to consumers.<sup>83</sup> As described in internal Forest documents, Forest “published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR” as of August 15, 2014, and “urg[ed] caregivers to speak with their loved ones’ ‘healthcare provider[s] as soon as possible to discuss switching to NAMENDA XR.”<sup>84</sup>

38. Forest took additional steps to limit the availability of Namenda IR to its largest customer base – Medicare patients.<sup>85</sup> I understand that on February 18, 2014, Forest informed the Center for Medicare and Medicaid Services (“CMS”) of its intention to discontinue sales of Namenda IR as of August 15, 2014, noting that CMS ought to remove Namenda IR from its 2015 Formulary Reference File (“FRF”).<sup>86</sup>

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<sup>81</sup> Complaint at ¶¶158-173. Because Namenda XR is listed separately in the Orange Book, by converting patients to Namenda XR, Forest could prevent generic substitution because generic Namenda IR would not be AB-rated to, and therefore not substitutable for, branded Namenda XR.

<sup>82</sup> Complaint at ¶180. See also, FRX-AT-01614465-66, FRX-AT-01614463-64, FRX-AT-01614461-62, FRX-AT-01614455-56.

<sup>83</sup> Forest Laboratories, Inc., “Forest Laboratories to Discontinue NAMENDA® Tablets, Focus on Once-Daily NAMENDA XR®,” *BusinessWire*, February 14, 2014. Available at <http://www.businesswire.com/news/home/20140214005829/en/Forest-Laboratories-Discontinue-NAMENDA%C2%AE-Tablets-Focus-Once-Daily>; Complaint at ¶174. Forest also notified the FDA of its intention to discontinue sales of Namenda IR as of August 15, 2014, on February 14, 2014. See FRX-AT-04519466-67; FRX-AT-01821687-89; Complaint at ¶174.

<sup>84</sup> FRX-AT-01775327-28; FRX-AT-01775329-330; FRX-AT-01794662-4797 at 01794712-13 (NYAG Opinion).

<sup>85</sup> 30(b)(6) Deposition of Mark Devlin, August 29, 2017 (hereafter “Forest 30(b)(6) Deposition”) at 233:21-234:6. (For Namenda, “a large percentage of the business...is paid for through the Medicare Part D program, and there’s just a small number of approved plan sponsors that we negotiate with for formulary coverage or access to our products.”)

<sup>86</sup> FRX-AT-04380946-47; Complaint at ¶179.

39. Due to concerns regarding the availability of Namenda XR, Forest issued a statement on June 10, 2014, delaying the removal of Namenda IR to the Fall of 2014.<sup>87</sup> Despite this delay, Forest still maintained publicly that the discontinuation of Namenda IR was imminent so as to continue to exert pressure on physicians and patients to switch to Namenda XR. On November 5, 2014, the company issued a press release stating that Namenda XR was now being produced “at capacities sufficient to support transitioning all Namenda IR twice daily tablet patients to its Namenda XR® once-daily product.”<sup>88</sup>

40. Based on my review of Plaintiffs’ allegations in this matter, the materials produced, as well as my training and experience in economics, I understand that the intended effect of the actions discussed above was to forestall entry of generic memantine, prevent Namenda from falling off the “patent cliff,” and preserve the large sales and profits Forest enjoyed on Namenda.

#### **IV. Analysis of Proposed Class Members**

41. I have been asked by Counsel for Plaintiffs to identify members of the proposed Class based on certain assumptions related to the date at which generic entry would have occurred and the date at which Namenda XR would have been introduced into the market, absent the alleged misconduct. I have also been asked to determine the magnitude of aggregate and individual damages suffered by proposed Class members under various measures, as discussed below and summarized in Exhibit 1 attached to this report.

42. Proposed Class members include wholesalers, retailers, and other middlemen (both large and small) who purchased memantine hydrochloride directly from Defendants and/or generic manufacturers in this matter. During the proposed Class Period, proposed Class members supplied memantine hydrochloride to all cross-sections of the patient community, responding to pharmacy-level and long-term care facility demand derived from patient demand. This means that demand for memantine hydrochloride is reflected in the volumes and market share of Namenda IR, Namenda XR, and generic Namenda IR purchased by proposed Class members. Recognizing that the vast majority of customers

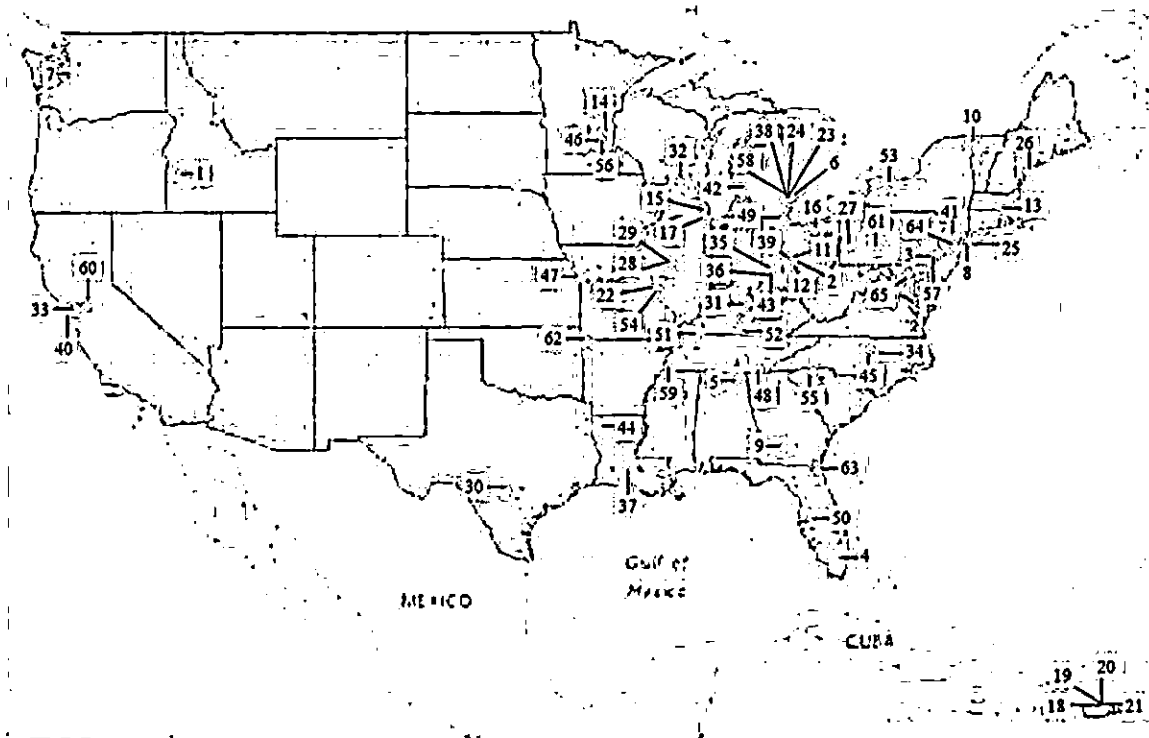
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<sup>87</sup> Complaint at ¶183; FRX-AT-03813904-05.

<sup>88</sup> FRX-AT-01783493-3514 at 3495.

would have purchased generic Namenda IR under competitive conditions at competitive prices (i.e., absent Defendants' alleged misconduct), there is no reason to assume that any individual proposed Class member would have served only the small fraction of the customer base that would not have taken advantage of the availability of a lower-priced generic. In other words, it is highly likely that each proposed Class member served customers that would have switched to generic Namenda IR in a competitive market free of the Defendants' alleged misconduct.

**Figure 1**  
**Map of Proposed Class Members**



Legend		
1 ALBERTSONS LLC	23 FIRST VETERINARY SUPPLY	45 NORTH CAROLINA MUTUAL WHOLESALE DRUG
2 AMERICAN HEALTH PACKAGING	24 FRANK W KERR INC	46 OPTUMRX INC
3 AMERISOURCEBERGEN CORPORATION	25 GENETCO INC	47 PBA HEALTH
4 ANDA INC	26 HANNAFORD BROTHERS	48 PEYTONS
5 ASSOCIATED PHARMACIES	27 HC PHARMACY CENTRAL INC	49 PRESCRIPTION SUPPLY INC
6 AUBURN PHARMACEUTICAL	28 HD SMITH LLC	50 PUBLIX SUPER MARKETS INC
7 BARTELL DRUGS COMPANY	29 HD SMITH WHOLESALE DRUG COMPANY	51 QUEST PHARMACEUTICALS, INC.
8 BELLCO DRUG CORPORATION	30 HE BUTT	52 RICHIE PHARMACEUTICAL COMPANY
9 BLOODWORTH WHOLESALE DRUGS	31 HUMANA INC	53 ROCHESTER DRUG COOPERATIVE INC
10 BURLINGTON DRUG COMPANY	32 INDEPENDENT PHARMACY COOPERATIVE	54 RX OUTREACH
11 CAPITAL WHOLESALE DRUG CO	33 KAISER PERMANENTE	55 SMITH DRUG COMPANY
12 CARDINAL HEALTH PHARMACEUTICAL	34 KERR DRUG INC	56 SUPERVALU INC
13 CVS CAREMARK	35 KEYSOURCE MEDICAL, INC.	57 TEL DRUG OF PA LLC JOANN CHRISTENS
14 DAKOTA DRUG INC	36 KROGER INC	58 THE HARVARD DRUG GROUP LLC
15 DIK DRUG COMPANY	37 LOUISIANA WHOLESALE DRUG COMPANY	59 TOPRX LLC
16 DISCOUNT DRUG MART INC	38 MAJOR PHARMACEUTICALS/RUGBY LABORAT	60 VALLEY WHOLESALE DRUG COMPANY INC
17 DMS PHARMACEUTICAL GROUP	39 MASTERS PHARMACEUTICAL INC.	61 VALUE DRUG COMPANY
18 DROGUERIA BETANCES INC	40 MCKESSON CORPORATION	62 WALMART
19 DROGUERIA CENTRAL INC	41 MEDCO HEALTH SOLUTIONS INC	63 WINN DIXIE LOGISTICS INC
20 DROGUERIA CESAR CASTILLO	42 MEIJER INC	64 BLUPAX PHARMACEUTICALS LLC
21 DRUGS UNLIMITED, INC.	43 MIAMI LUKEN INC	65 HEALTHSOURCE DISTRIBUTORS LLC
22 EXPRESS SCRIPTS INC	44 MORRIS & DICKSON COMPANY LLC	

## V. Common Evidence of Antitrust Impact

### A. *The Relevant Antitrust Product Market is Memantine Hydrochloride*

43. In order to determine whether members of the proposed Class would have been injured as a result of the misconduct alleged by Plaintiffs, an economic analysis must define the relevant antitrust product and geographic markets at issue. I understand the Court has held that in this matter that Forest is collaterally estopped regarding the relevant market and its monopoly power.<sup>89</sup> The Court noted that, in the prior NYAG matter, “Judge Sweet concluded that the relevant ‘geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States’” and “prior to the upcoming entry of generics in the U.S. market, Forest was ‘the exclusive producer[] of all forms of memantine,’ meaning that Forest ‘[has] monopoly power.’”<sup>90</sup> I therefore understand that “Forest is precluded from relitigating the question[] of (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition.”<sup>91</sup> While I understand that the issue of Forest’s monopoly power has been decided, I nevertheless analyzed the issue, which I discuss in more detail below.

44. Based on my own analysis of the documents and data produced in this litigation, as well as my training and experience in economics, I have concluded that the relevant antitrust product market with respect to the alleged misconduct is the market for memantine hydrochloride. I have also concluded that the United States constitutes the relevant antitrust geographic market for evaluating the alleged misconduct. I discuss my reasons for these conclusions below.

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<sup>89</sup> See United States District Court Southern District of New York, *In Re Namenda Direct Purchaser Antitrust Litigation*, Memorandum Decision and Order Granting in Part and Denying in Part Plaintiffs’ Motion for Collateral Estoppel and Partial Summary Judgment on Count One; Denying Plaintiffs’ and Defendants’ Motions for Partial Summary Judgment on Count Five, May 23, 2017 (hereafter “Collateral Estoppel Order”) at pp. 15, 21, 33.

<sup>90</sup> Collateral Estoppel Order, p. 21.

<sup>91</sup> Collateral Estoppel Order, p. 33.

i. The Relevant Antitrust Product Market is the Market for Memantine Hydrochloride Products

45. In economics, market power is defined as a firm's ability to set prices above competitive levels without losing significant sales to competitors. Economists often assess market power by defining a relevant market - the smallest possible set of goods for which a hypothetical monopolist could exercise market power to raise prices on that set of products by a small, but significant, amount without losing so much in sales volume that the increase in price is unprofitable.<sup>92</sup> In general, an economic analysis of the relevant antitrust product market requires identifying "products that are close demand or supply substitutes,"<sup>93</sup> typically moving outward from the narrowest set of products to increasingly broader groups of goods. To determine the lack of economic substitutability between or among certain products, economists often consider "practical indicia," or evidence of market participants' recognition of the relevant market as a separate economic entity.<sup>94</sup> Practical indicia can include industry or public recognition of the market as a relevant market, peculiar characteristics and uses unique to the product at issue, or distinct customers.<sup>95</sup> Practical indicia that consumers do or do not switch between or among certain products in response to increases or decreases in price (i.e.,

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<sup>92</sup> One of the tools economists rely upon in defining relevant antitrust product and geographic markets is the so-called "SSNIP" test. A SSNIP test is based upon a hypothetical "small but significant and non-transitory increase in price," as described in the Horizontal Merger Guidelines. The SSNIP test is used by the FTC and the DOJ to define relevant economic markets. The SSNIP test is intended to ascertain whether a hypothetical monopolist can exercise market power in a relevant product or geographic market. If the hypothetical monopolist is able to raise prices for a product or group of products by a "small but significant" amount, usually assumed to be 5-10 percent, for a non-transitory period (usually assumed to be one year) without losing so much in sales volume that the increase in price is unprofitable, then that product or group of products constitutes a relevant antitrust product market. See U.S. Department of Justice and the Federal Trade Commission, "Horizontal Merger Guidelines," August 19, 2010 (hereafter "Horizontal Merger Guidelines") at § 4.1.1. "Even when the evidence necessary to perform the hypothetical monopolist test quantitatively is not available, the conceptual framework of the test provides a useful methodological tool for gathering and analyzing evidence pertinent to customer substitution and to market definition." Horizontal Merger Guidelines at § 4.1.3.

<sup>93</sup> Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization*, Fourth Edition, Boston: MA, Pearson Addison Wesley, 2005 (hereafter "Carlton and Perloff") at p. 646. "Product B is a demand substitute for A if an increase in the price of A causes consumers to use more B instead. Product B is a supply substitute for A if, in response to an increase in the price of A, firms that are producing B switch some of their production facilities to the production of A." See also, Horizontal Merger Guidelines at § 4.

<sup>94</sup> A SSNIP test is essentially a measure of cross-price elasticity of demand or the amount by which the quantity demanded of one product changes as a result of a change in the price of a possible economic substitute for that product. See Carlton and Perloff at pp. 646-648. This same passage also discusses an economist's reliance on practical indicia for defining product markets.

<sup>95</sup> See, for example, *United States v. Brown Shoe Co.*, 370 U.S. 294 (1962).

cross-price elasticity of demand) are highly probative. The use of practical indicia in defining relevant antitrust product markets has a well-established background in merger analysis including well-known proposed mergers Whole Foods/Wild Oats and Staples/Office Depot.<sup>96</sup> Based on my research into the market for memantine hydrochloride and my training and experience in economics, I have determined that there are practical indicia which indicate that memantine hydrochloride constitutes a relevant antitrust product market in that a monopolist who controlled the supply of memantine hydrochloride could profitably raise prices by 5 to 10 percent over a sustained period of time without losing sales to the extent that a price increase would no longer be profitable. I discuss the bases for this conclusion below.

a. There Are No Functional Substitutes for Memantine Hydrochloride

46. As part of my analysis of the relevant antitrust product market, I considered whether there are drugs used to treat Alzheimer's disease that could reasonably be substituted for memantine hydrochloride. As I discuss below, evidence I have reviewed demonstrates that there are no functional substitutes for memantine hydrochloride.

47. I understand that the FDA has approved five drugs for the treatment of Alzheimer's disease: Aricept, Cognex (discontinued), Exelon, Namenda, and Razadyne.<sup>97</sup> I understand that the four remaining drugs are part of a separate drug class of "cholinesterase inhibitors" ("CIs")<sup>98</sup> and "work in essentially the same manner"<sup>99</sup> by "reduc[ing] the breakdown in the brain of a chemical called acetylcholine, a chemical

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<sup>96</sup> See, for example, United States District Court for the District of Columbia, *Federal Trade Commission, v. Whole Foods Market, Inc., and Wile Oats Markets, Inc.*, Civil Action No. 1:07-cv-01021-PLF, Plaintiff Federal Trade Commission's Corrected Brief on Its Motion for Preliminary Injunction, August 1, 2007 at p. 18; Carlton Varner and Heather Cooper, "Product Markets in Merger Cases: The Whole Foods Decision," *The Antitrust Source*, October 2007.

<sup>97</sup> FRX-AT-01726785-792 at 785; FRX-AT-01731390-1541 at 1403; FRX-AT-01730731-740 at 735. In May 2015, Actavis launched Namzaric, its fixed dose combination of memantine hydrochloride and donepezil. During the period from May 2015 to July 2015, Namzaric achieved modest sales and had little significant impact on the sales of Namenda IR and Namenda XR. Namzaric has had no discernible impact on the rate of penetration after the launch of generic memantine hydrochloride in July 2015. I have seen no evidence that indicates that there has been any significant impact on the price of Namzaric from the launch of generic memantine hydrochloride. Moreover, since it was not available until May 2015, Namzaric by definition could not have had any effect on Forest's market power in earlier periods, and finally, Actavis (Forest) controls both Namzaric and branded Namenda, and so even if both drugs were included in a relevant market, Actavis' share would be the sum of both.

<sup>98</sup> FRX-AT-01726785-792 at 785-786.

<sup>99</sup> FRX-AT-01726785-792 at 785.

messenger that transmits information between nerve cells.”<sup>100</sup> Namenda (branded memantine hydrochloride), on the other hand, is in a separate class of drugs as it works differently from a CI.<sup>101</sup> As noted above, Namenda is an NMDA antagonist, which works by:

...thwart[ing] the overstimulation of glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. Excessive glutamate activity in mid-stage and late stage Alzheimer’s patients is believed to interfere with neurotransmission, contributing to neurodegeneration.<sup>102</sup>

According to a September 2013 Namenda Franchise Business Plan, the “Alzheimer’s market consists of only two classes of drugs that provide symptomatic treatment. These classes do possess different mechanisms of actions. AChEIs work on the acetylcholine pathway while Namenda works on the glutamate pathway.”<sup>103</sup>

48. Given that Namenda is part of a separate drug class and possesses a different mechanism of action than CIs, it is typically prescribed for different stages of Alzheimer’s disease. For example, because the efficacy of CIs decreases as the disease progresses, CIs are most commonly prescribed for patients with mild to moderate Alzheimer’s disease.<sup>104</sup> In contrast, Namenda is most commonly prescribed to patients with moderate to late-stage Alzheimer’s disease.<sup>105</sup>

49. In many cases, Namenda is prescribed in combination with other CI drugs for the treatment of Alzheimer’s disease.<sup>106</sup> According to the National Institute of Health’s National Institute on Aging, “[b]ecause NMDA antagonists work very differently from cholinesterase inhibitors, the two types of drugs can be prescribed in combination.”<sup>107</sup> According to Forest, the “Namenda franchise of products can be used as monotherapy or in combination. Namenda or Namenda XR in combination with AChEIs has

<sup>100</sup> FRX-AT-01726785-792 at 786.

<sup>101</sup> FRX-AT-01726785-792 at 786.

<sup>102</sup> FRX-AT-01726785-792 at 786.

<sup>103</sup> FRX-AT-01730731-740 at 736.

<sup>104</sup> FRX-AT-01726785-792 at 786. See, also, 2017 National Institute on Aging.

<sup>105</sup> FRX-AT-01726785-792 at 786; 2017 National Institute on Aging.

<sup>106</sup> FRX-AT-01780843-44 at 43.

<sup>107</sup> 2017 National Institute on Aging.



demonstrated proven benefits over AChEI monotherapy.”<sup>108</sup> In its September 2013 Namenda Franchise Business Plan, Forest estimated that 70 percent of Namenda prescriptions are written in combination with a CI.<sup>109</sup> As described by Dr. James Lah, Associate Professor of Neurology at Emory University and Clinical Core Leader of the Emory Alzheimer’s Disease Research Center, in his Declaration in the NYAG matter: “I typically begin therapy with a CI, and then add Namenda as the disease progresses. Almost all of my patients who take Namenda also take a CI.”<sup>110</sup>

50. The fact that memantine hydrochloride products (such as Namenda) and CIs are in separate therapeutic drug classes with different mechanisms of action constitutes one piece of common evidence demonstrating that memantine hydrochloride constitutes a relevant antitrust product market. Given the differences in these drugs and how they are used to treat Alzheimer’s disease, it is unlikely that a small but significant increase in the price of Namenda would lead to an unprofitable loss in sales volume as a result of Alzheimer’s patients switching to CIs for their treatment. This conclusion is further illustrated by the fact that a large percentage of memantine hydrochloride prescriptions are written in combination with CIs. Patients being treated with both types of drugs would not be expected to substitute Namenda with a CI in response to a small but significant increase in the price of Namenda because they are already taking a CI. As Dr. Lah noted, Namenda and CIs “are not interchangeable; rather, they seem to have the greatest beneficial effect when they are used together.”<sup>111</sup> Having determined that Namenda and CIs are not interchangeable, Dr. Lah concluded that “there are no therapeutic substitutes for Namenda currently on the market” to the best of his knowledge.<sup>112</sup>

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<sup>108</sup> FRX-AT-01730731-740 at 735.

<sup>109</sup> FRX-AT-01730731-740 at 736. I understand that on October 13, 2006, the FDA approved the use of Aricept for the treatment of severe Alzheimer’s Disease. See U.S. Food and Drug Administration, “FDA Approves Expanded Use of Treatment for Patients With Severe Alzheimer’s Disease,” October 13, 2006 (hereafter “Aricept FDA Press Release”). However, in its September 2013 Namenda Franchise Business Plan, Forest noted since “Aricept [a CI] is indicated for mild patients it is usually initiated first. Namenda is usually added when the patient progresses to the moderate stage of the disease.” See FRX-AT-01730731-740 at 736.

<sup>110</sup> FRX-AT-01726785-792 at 786.

<sup>111</sup> FRX-AT-01726785-792 at 786.

<sup>112</sup> FRX-AT-01726785-792 at 785-786. In the prior NYAG matter, Defendants retained Dr. Jerry Hausman to opine on “economic issues related to Forest’s plan to restrict the distribution of Namenda ® IR.” In his

b. Namenda Volume and Sales Were Unaffected by Generic Donepezil

51. In addition to the lack of functional substitutes, evidence I have reviewed indicates that Namenda sales were unaffected by the introduction of generic equivalents to Aricept in November 2010. This constitutes an additional piece of practical indicia demonstrating that memantine hydrochloride constitutes a relevant antitrust product market.

52. As I previously discussed, Aricept (co-promoted by Pfizer Inc. and Eisai Inc.) is a CI drug with the active ingredient donepezil that, since October 2006, has been approved by the FDA to treat all stages of Alzheimer's disease.<sup>113</sup> On November 30, 2010, Ranbaxy (acquired by Sun in March 2015) announced that "it had received FDA approval to launch generic Aricept," initiating a six-month period of exclusivity to market its generic product.<sup>114</sup> In June 2011, following Ranbaxy's six months of exclusivity, several additional generic manufacturers began marketing generic donepezil products.<sup>115</sup>

53. As I discuss in greater detail below, there is an extensive body of published research concerning the effects of generic competition in pharmaceutical markets. These studies show that when AB-rated generic products enter the market, they typically do so at lower prices than their brand-name counterparts and capture a significant share of the total unit sales for the drug. I also discuss studies demonstrating that the price differential (generic versus the brand name drug) and the generic's share of unit sales increase over time following generic entry. With respect to generic donepezil, evidence I have reviewed demonstrates that, following Ranbaxy's six-month period of exclusivity, multiple generic manufacturers began marketing generic donepezil products priced at

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report, Dr. Hausman did "not offer any opinion on the relevant product market," and assumed that the "relevant product market is as defined in the complaint (NMDA antagonists)." See FRX-AT-01746793-6804 at 6794. Defendants also retained Dr. Pierre-Yves Cremieux to opine on economic issues in connection to the related NYAG matter, including relevant product market. I have reviewed the opinions contained in Dr. Cremieux's Declaration in the NYAG matter with respect to relevant product market. None of opinions contained therein has caused me to change my conclusion that the relevant antitrust product market with respect to the alleged misconduct is the market for memantine hydrochloride products.

<sup>113</sup> Aricept FDA Press Release; 2017 National Institute on Aging; See Pfizer, Aricept® (Donepezil Hydrochloride.) Available at <http://www.pfizer.com/products/product-detail/aricept>.

<sup>114</sup> FRX-AT-04217620-22 at 20; Sun Pharma, Sun Pharma – Ranbaxy Merger. Available at <http://www.sunpharma.com/investors/archives/sunpharma-ranbaxy-merger>.

<sup>115</sup> FRX-AT-04217620-22 at 20.

“pennies per pill.”<sup>116</sup> Further, one month after generic entry (December 2010), the substitution rate of generic donepezil (generic for brand) had reached 70 percent, ultimately climbing as high as 95 percent by September 2011.<sup>117</sup>

54. The effect of the availability of generic donepezil products beginning in November 2010, and, in particular, multiple generic donepezil products beginning in June 2011, provides a natural test as to whether or not memantine hydrochloride constitutes a relevant antitrust product market. That is, if NMDA antagonists and CIs were part of the same relevant antitrust product market, then, as a matter of economics, I would expect Forest to lose a significant volume of Namenda sales once lower-priced generic donepezil became available as consumers would substitute less expensive generic donepezil for their purchases of higher-priced Namenda. Common evidence I have reviewed demonstrates that this was not the case. Rather, evidence indicates that sales of Namenda were unaffected by the significantly lower prices for donepezil in the marketplace, further supporting my conclusion that memantine hydrochloride constitutes a relevant antitrust product market.

55. Evidence that Namenda sales were unaffected by the introduction of lower-priced generic donepezil includes notes from a January 25, 2012 Forest Managers’ Meeting stating that “the generic Aricept entry has had no negative impact on Namenda... In fact... trends continue to be positive for Namenda’s use in combination with Aricept, just as we had expected.”<sup>118</sup> Similarly, in a late 2011 Forest presentation titled “Impact of Generic Donepezil,” Forest analyzed the effect of Aricept’s loss of exclusivity on Namenda sales.<sup>119</sup> In that presentation, Forest concluded that Aricept’s loss of exclusivity had a “[m]inimal” effect on its volume and share of Namenda.”<sup>120</sup> Forest further noted that the “Namenda TRx volume fluctuations are within normal range as is Namenda share,” during this time.<sup>121</sup>

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<sup>116</sup> FRX-AT-04217620-22 at 20.

<sup>117</sup> FRX-AT-03868069-073 at 079.

<sup>118</sup> FRX-AT-01652323-29 at 23; FRX-AT-01652322; FRX-AT-01606118-134.

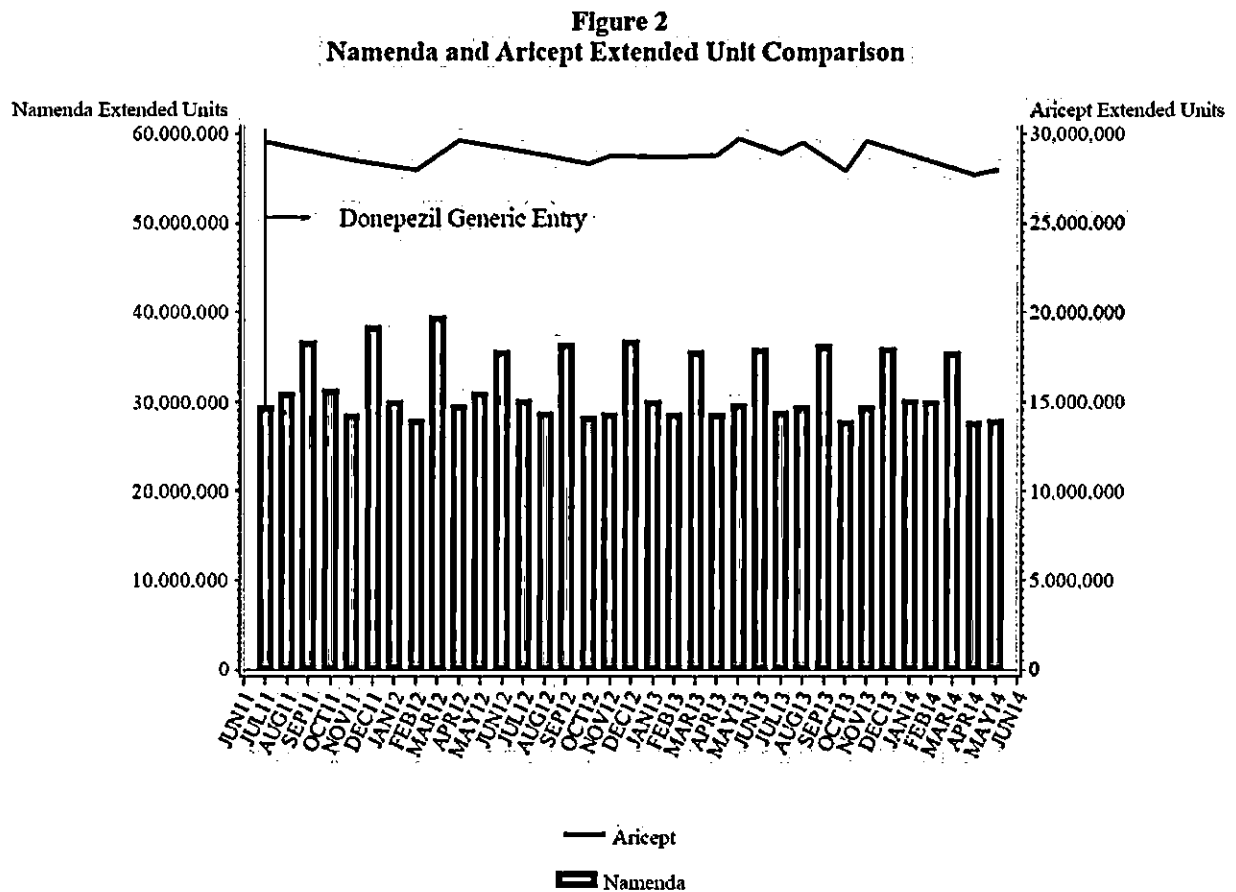
<sup>119</sup> FRX-AT-03868069-079.

<sup>120</sup> FRX-AT-03868069-079 at 072.

<sup>121</sup> FRX-AT-03868069-079 at 072.

56. The fact that the launch of generic donepezil had a “minimal” impact on Namenda sales volumes is one piece of evidence indicating that CIs and memantine hydrochloride are not economic substitutes. This further demonstrates that memantine hydrochloride constitutes a relevant antitrust product market.

57. Figure 2 below demonstrates sales volumes for Aricept (branded and generic) and Namenda IR in terms of extended units from June 2011 (the month when multiple generic manufacturers of donepezil entered the market) through June 2014. As shown, Namenda IR sales volumes remained steady following the entry of multiple generic manufacturers of donepezil, further demonstrating that the entry of generic donepezil did not have a significant impact on Namenda sales volumes.



Source: NSP Data.

c. Forest's Prices for Namenda Greatly Exceeded Marginal Costs

58. Another indication of Forest's market power is the fact that Namenda prices were set well above marginal costs. For example, in a Namenda financial analysis for fiscal years 2011 through 2014, Namenda achieved net operating margins (as calculated by Forest as net operating income as a percentage of net sales) of 68.4 percent, 69.0 percent, 67.2 percent, and 73.2 percent in 2011, 2012, 2013, and 2014, respectively.<sup>122</sup> In a fiscal year 2009 Namenda performance overview, Forest reported that its latest estimate of fiscal year 2009 net operating margin as 58.1 percent.<sup>123</sup> If Forest had not dominated the relevant antitrust product market for memantine hydrochloride, it would not have been able to raise prices above marginal cost to supra-competitive levels. Economic theory teaches that in the absence of market power, a firm's prices are driven to the cost of production.<sup>124</sup> This is another indication that memantine hydrochloride constitutes a relevant antitrust product market.

ii. The Relevant Antitrust Geographic Market is the United States

59. In addition to defining the relevant antitrust product market, relevant market analysis also includes defining the geographic scope of the market in which the product at issue is sold. As discussed above, the FDA regulates the sale of branded, generic, and over-the-counter drugs across the U.S. In the case of memantine hydrochloride, this constitutes evidence that the relevant antitrust geographic market is the entire United States. My conclusion that the relevant antitrust geographic market is the United States is also based on the geographic scope of direct purchasers (including proposed Class members) of Namenda IR, Namenda XR, and generic memantine hydrochloride. That is, the fact that direct purchasers of branded and generic Namenda operate on a national basis is further evidence that relevant antitrust geographic market in this case is the United States.

*B. Forest Possessed Monopoly Power in the Memantine Hydrochloride Market*

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<sup>122</sup> FRX-AT-01711279.

<sup>123</sup> FRX-04008540-42 at 40.

<sup>124</sup> Carlton and Perloff at pp. 642-643.

*Prior to the Launch of Any Generic AB-Rated Bioequivalent Products*

60. I demonstrated above that the relevant market at issue in this case is the market for memantine hydrochloride in the United States. This means that a monopolist who controlled a large share of memantine hydrochloride sales could raise price well above competitive levels without fearing a large enough loss in sales such that a price increase would become unprofitable. The monopoly power possessed by such a hypothetical monopolist is defined by one standard economic textbook as follows:

In contrast to a price-taking competitive firm, a monopoly knows that it can set its own price and that the price chosen affects the quantity it sells. A monopoly can set its price above its marginal cost but does not necessarily make a supracompetitive profit. For example, if a monopoly incurs a fixed cost, its profit may be zero (the competitive level) even if its price exceeds its marginal cost. It is common practice to say that whenever a firm can profitably set its price above its marginal cost without making a loss, it has *monopoly power or market power*.<sup>125</sup>

61. Put another way, monopoly power refers to the ability of a firm to persistently price at a level that is significantly higher than the competitive price. Whether a firm has market power is often assessed through an analysis of market share and barriers to entry. That is, a firm that controls a dominant share of sales in a relevant market characterized by high barriers to entry is often considered to possess monopoly power.

62. I discuss below evidence I have reviewed demonstrating that Defendant Forest possessed monopoly power in the memantine hydrochloride market prior to the launch of AB-rated generic alternatives in July 2015 – and including the entire time period of the alleged unlawful delay of generic competition. As I explain, because Forest possessed market power in the relevant antitrust product and geographic market prior to generic entry in 2015, it was able to price above competitive levels. This means that entry of AB-rated generic substitutes for Namenda would be expected to drive memantine hydrochloride prices down to the level of marginal cost. In fact, I observe this sharp decline in prices in the memantine hydrochloride market in the U.S. after generics entered in July 2015.

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<sup>125</sup> Carlton and Perloff at p. 93.

- i. Forest Controlled 100 percent of the Memantine Hydrochloride Market Prior to the Launch of Any Generic AB-Rated Bioequivalent Products

63. Evidence I have reviewed demonstrates that Forest controlled 100 percent of the memantine hydrochloride market prior to generic entry in July 2015. As a matter of economics, this would have allowed Forest to raise prices for Namenda substantially above competitive levels. As I previously discussed, prior to generic entry in July 2015, Namenda IR and Namenda XR (both manufactured by Forest) were the only memantine hydrochloride products available in the market. Further, as I previously discussed, the fact that memantine hydrochloride constitutes a relevant antitrust product market means that Namenda IR and Namenda XR did not face competition from other drugs used to treat Alzheimer's such as CIs. This lack of competition allowed Forest to control 100 percent of the memantine hydrochloride market prior to generic entry in July 2015, which allowed it to profitably set prices for Namenda above competitive levels.

- ii. The Regulatory Structure Governing Drug Sales Provides a Barrier to Market Entry

64. As discussed above, the FDA grants patent protection to new drug manufacturers in order to incentivize innovation. By awarding a temporary monopoly over product sales, patents allow developers to recoup their research and development costs. This temporary monopoly power works as a barrier to entry preventing competitors from entering the market and undercutting the developer on price. This is in addition to the barriers to entry created by the time and resource-intensive research and development associated with commercializing a new drug.

*C. Defendants' Anticompetitive Conduct Impacted All Members of the Proposed Class Under the No Reverse-Payment But-For World*

65. As I discussed above, I understand that Plaintiffs allege that Forest entered into an unlawful "pay-for-delay" or "reverse payment" agreement with Mylan in 2010, and settled with other generic competitors as well in 2009-2010, to delay generic competition for Namenda IR, and thereby delaying the rapid loss of branded Namenda IR sales and sharp drop in price that would predictably result from generic entry. Plaintiffs allege that this delay allowed Forest to continue to charge supracompetitive prices for Namenda IR

and also bought time for Forest to plan, announce and implement a “hard switch” from Namenda IR to Namenda XR, before the (delayed) generic competition for Namenda IR could begin. The hard switch, Plaintiffs allege, impaired generic competition because generic Namenda IR would not be, and is not, AB-rated to Namenda XR, and by the time generic Namenda IR belatedly became available in 2015, the base of Namenda IR prescriptions would be (and was) smaller due to the hard switch and, consequently, generic sales and their attendant cost savings would be, and were, suppressed, causing Class members to be overcharged.

66. As previously discussed, state laws allow (and in some cases require) the substitution of generic memantine hydrochloride by pharmacists for brand-name Namenda once the AB-rated generic became available and was listed in the Orange Book, even in cases where the doctor had written a prescription for the brand-name.<sup>126</sup> In addition to the substitution of generic memantine hydrochloride mandated under state laws, many patients taking Namenda would have switched to generic memantine hydrochloride as soon as it became available as a result of the various mechanisms employed by managed care entities to promote generic substitution.<sup>127</sup> Generic substitution laws and cost-saving policies of managed care entities and other third-party payers mean that generic substitution (substitution of AB-rated generics for the brand) is very rapid and, consequently, direct purchasers also switch from the brand to the generic in order to meet this market demand. Hence, conduct that delays or impairs generic competition causes direct purchasers to be overcharged because instead of purchasing the lower-priced generic, they are forced to purchase the higher priced brand. Had generic competition begun earlier and/or not been impaired by the hard switch, Class members would have purchased generic Namenda IR earlier and in higher amounts, all at lower prices than the prices at which they purchased branded Namenda IR and/or XR.

67. My conclusion that Defendants’ alleged misconduct impacted all or nearly all proposed Class members can be established using economic analyses and generalized

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<sup>126</sup> Complaint at ¶46; CBO Study at p. 7; FTC Consumer Information, Generic Drugs and Low-Cost Prescriptions, July 2012. Available at <http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions#getting>.

<sup>127</sup> CBO Study at pp. 8, 29.



evidence common to the proposed Class as a whole rather than specific to individual members. This conclusion is based on the following conclusions concerning the market for memantine hydrochloride including branded Namenda and generic memantine hydrochloride:

- a. There is an extensive body of published research concerning the effects of generic competition in pharmaceutical markets. These studies show that when AB-rated generic products enter the market, they typically do so at lower prices than their brand name counterparts and also capture a significant share of the total unit sales for the drug.<sup>128</sup> As a result, direct purchasers derive significant cost savings by switching to the lower priced AB-rated generic product.
- b. Defendants' documents and forecasts regarding the effects of generic competition in the market for memantine hydrochloride products confirm my conclusion that when lower-priced AB-rated generics enter the market, they tend to capture most prescriptions for the corresponding branded drug, resulting in significant cost savings for direct purchasers.
- c. Namenda and generic memantine hydrochloride sales data from IMS as well as transaction-level data from Forest and generic memantine hydrochloride manufacturers confirm the findings from the numerous studies concerning the effect of generic entry on prices for brand pharmaceuticals and the market share of the brand following generic entry.
- d. Also, as I explained above, the proposed Class members include wholesalers, retailers, and middlemen (both large and small) who purchased memantine hydrochloride directly from Defendants and/or generic manufacturers in this matter. During the proposed Class Period, proposed Class members supplied memantine hydrochloride to

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<sup>128</sup> Total unit sales for the drug include the unit sales of the brand name drug plus the unit sales of the AB-rated generic.

all cross-sections of the patient community, responding to pharmacy-level and long-term care facility demand derived from patient demand. This means that demand for memantine hydrochloride is reflected in the volumes and market share of Namenda IR, Namenda XR, and generic Namenda IR purchased by proposed Class members. Recognizing that the vast majority of customers would have purchased generic Namenda IR under competitive conditions at competitive prices (i.e., absent Defendants' alleged misconduct), there is no reason to assume that any individual proposed Class member would have served only the small fraction of the customer base that would not have taken advantage of the availability of a lower-priced generic. In other words, it is highly likely that each proposed Class member served customers that would have switched to generic Namenda IR in a competitive market free of the Defendants' alleged misconduct.

I discuss these conclusions in more detail below.

i. Economic Effects of Generic Entry

68. I have reviewed a number of published, peer-reviewed economic studies by government and academic researchers concerning the effects of generic competition in pharmaceutical markets. These studies demonstrate that when AB-rated generics enter the market, they typically do so at lower prices than their brand-name counterparts and thereby capture a significant share of the total unit sales for the drug (brand plus generic). Other studies show that the price differential (generic versus the brand name drug) and the generic's share of unit sales increase over time following generic entry. The price differential and the evolution of market shares over time tend to follow a similar pattern for a number of prescription drugs. These studies include, but are not limited to, the following:

- a. CBO, "A CBO Study: How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998.

- b. Henry Grabowski and John Vernon, “Longer Patents for Increased Generic Competition in the U.S.: The Hatch-Waxman Act after One Decade,” *PharmacoEconomics*, v.10, Suppl 2, 1996 at pp. 110-23.
- c. Atanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg and Oded Bizan, “Generic Competition in the US Pharmaceutical Industry,” *International Journal of the Economics of Business*, Vol. 13, No. 1, 2006 at pp. 15-38.
- d. Joseph Farrell, David J. Balan, Keith Brand and Brett W. Wendling, “Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets,” Published Online, Springer Science+Business Media, LLC, October 1, 2011 at pp. 272-296.
- e. Duane Kirking, Frank Ascione, Caroline Gaither and Lynda Welage, “Economics and Structure of the Generic Pharmaceutical Industry,” *Journal of the American Pharmaceutical Association*, Vol.41, No. 4, 2001 at pp. 578-584.
- f. Ernst Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece and Edward Tuttle, “Authorized Generic Drugs, Price Competition, and Consumer’s Welfare,” *Health Tracking*, Vol. 26, No. 3, 2007 at pp. 790-799.
- g. David Reiffen and Michael Ward, “Generic Drug Industry Dynamics,” *The Review of Economics and Statistics*, Vol. 87, No. 1, February 2005 at pp. 37-49.
- h. FDA, “Generic Competition and Drug Prices,” March 13, 2010.<sup>129</sup>

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<sup>129</sup> Available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

- i. FTC, “Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,” January 2010.<sup>130</sup>
- j. Henry Grabowski, Margaret Kyle, Richard Mortimer, Genia Long, and Noam Kirson, “Evolving Brand-Name And Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act,” *Health Affairs*, Vol. 30, No. 11, November 2011 at pp. 2157-2166.

I discuss the findings of several of these publications below.

69. A 1998 CBO study analyzing the economic effects of generic competition using retail pharmacy data for 21 brand-name drugs found that “[w]ithin their first full calendar year after patent expiration, those drugs lost an average of 44 percent of their market (as measured by the quantity of prescriptions sold through pharmacies) to generic drugs. And the generic versions cost an average of 25 percent less than the original brand-name drugs at retail prices.”<sup>131</sup> Further, in calculating average retail prescription prices for generic and brand-name drugs in 1994, this study found that the average retail prescription price for a single source innovator drug was \$53.80 versus \$17.40 for a generic drug.<sup>132</sup> This represents a difference of over 65 percent between the price of the brand-name drug and the generic.

70. Grabowski and Vernon performed a similar analysis, examining the pattern of generic and brand-name prices for “products whose patents expired between 1984 and 1993.”<sup>133</sup> As the authors reported in their 1996 article, “[m]ajor brand name products now typically lose more than half their market share within the first year after patent expiration.”<sup>134</sup> Specifically, Grabowski and Vernon found that between 1984 and 1991, the prices of generic drugs one year following generic entry fell to less than 50 percent of

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<sup>130</sup> Available at <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>. (hereafter “Pay-for-Delay”).

<sup>131</sup> CBO Study at p. xiii. The CBO study relies on a variety of data, “including a data set that represents about 70 percent of prescription drug sales through retail pharmacies in the United States.” CBO Study at p. x.

<sup>132</sup> CBO Study at p. 15.

<sup>133</sup> Henry Grabowski and John Vernon, “Longer Patents for Increased Generic Competition in the U.S.: The Waxman-Hatch Act after One Decade,” *PharmacoEconomics*, v.10, Suppl 2, 1996 at pp.110-23 (hereafter “Grabowski and Vernon”) at p. 110.

<sup>134</sup> Grabowski and Vernon at p. 110.

the brand-name price.<sup>135</sup> After two years of generic competition, the generic price was less than 40 percent of the brand-name price.<sup>136</sup>

71. In 2006, Saha, Grabowski, Birnbaum, Greenberg and Bizan published a study analyzing data for 40 brand-name drugs that first experienced generic competition during the period July 1992 through January 1998.<sup>137</sup> The authors found that the average generic-to-brand price ratio was 54 percent and, on average, generic drugs had a 55 percent market share one year after generic entry.<sup>138</sup> This finding was reiterated in a 2011 study published by a group of economists at the FTC. There, the authors found that “generic products quickly take a large share of the market from the brand, earning between 55-70% of the revenue share during the first six months of entry.”<sup>139</sup> A similar estimation was performed in an article by Kirking, Ascione, Gaither, and Welage in which the authors found that “generics are typically priced 30% to 60% less than their brand counterparts, with reductions of as much as 80% in some cases.”<sup>140</sup>

72. I have also reviewed published economic research on the effects of generic entry that analyze the impact of the *number* of generic competitors on prices for generics and brand-name equivalents. For example, a study by Berndt, Mortimer, Bhattacharjya, Parece, and Tuttle concluded that an increase in the number of available generics leads to lower generic drug prices relative to brand-name prices and higher generic market share.<sup>141</sup> According to the study, however, this is true for up to four or five generic competitors as after the fourth or fifth generic equivalent the effect of additional generics on price and market share became “negligible.”<sup>142</sup> A study by Reiffen and Ward

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<sup>135</sup> Grabowski and Vernon at p. 113.

<sup>136</sup> Grabowski and Vernon at p. 113.

<sup>137</sup> Atanu Saha, Henry Grabowski, Howard Birnbaum, Paul Greenberg and Oded Bizan, “Generic Competition in the US Pharmaceutical Industry,” *International Journal of the Economics of Business*, Vol. 13, No. 1, 2006 (hereafter “Saha et al.”) at pp.15-35.

<sup>138</sup> Saha et al. at Table 1.

<sup>139</sup> Joseph Farrell, David J. Balan, Keith Brand and Brett W. Wendling, “Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets,” Published Online, Springer Science+Business Media, LLC, October 1, 2011 at pp. 272-296 at 286.

<sup>140</sup> Duane Kirking, Frank Ascione, Caroline Gaither and Lynda Welage, “Economics and Structure of the Generic Pharmaceutical Industry,” *Journal of the American Pharmaceutical Association*, Vol.41, No. 4, 2001 at pp. 578-84 at 580.

<sup>141</sup> Ernst Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece and Edward Tuttle, “Authorized Generic Drugs, Price Competition, and Consumer’s Welfare,” *Health Tracking*, Vol. 26, No. 3, 2007 (hereafter “Berndt et al.”) at pp. 790-799 at 792.

<sup>142</sup> Berndt et al. at p. 792.

confirms this finding, concluding that “the negative effect of increased competition on prices continues at least until the fifth firm enters, but is not likely to be important after the eighth firm enters.”<sup>143</sup> A similar study published by the FTC in 2010 found that, a year after generic entry, with multiple generic competitors, generic prices were 85 percent below the pre-generic brand price on average and 90 percent of prescriptions had switched from the brand to the generic.<sup>144</sup> Likewise, in 2015, a study by the FDA found that the average generic to brand price ratio tends to fall as additional generic manufacturers enter the market:

On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower.<sup>145</sup>

73. Taken as a whole, these peer-reviewed economic studies concerning the effects of generic competition in pharmaceutical markets establish that generic drugs sell at a significant discount to their brand-name counterparts and that as the number of generics increases that discount widens. The literature also establishes that generics capture a significant share of the total market for the drug (brand plus generic) from their brand-name counterparts following generic entry.

74. Based on my training and experience in economics and my review of the economic research on the effects of generic entry, I have concluded that the earlier entry of generic memantine hydrochloride into the market for memantine hydrochloride products would have resulted in substantially lower purchase prices. Conduct that delays or impairs generic competition, then, results in overcharges because purchasers continue paying the higher brand prices instead of the lower generic prices. Even taken by itself,

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<sup>143</sup> David Reiffen and Michael Ward, “Generic Drug Industry Dynamics,” *The Review of Economics and Statistics*, Vol. 87, No. 1, February 2005 at pp. 37-49 at 49.

<sup>144</sup> Pay-for-Delay at p. 8.

<sup>145</sup> FDA, “Generic Competition and Drug Prices,” May 13, 2015. Available at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

the economic literature concerning the price impacts of generic entry in pharmaceutical markets is sufficient evidence, common to the proposed Class, that Forest's alleged misconduct, assuming it delayed generic competition would have resulted in higher prices paid by all or nearly all Class members. In other words, had generic Namenda IR entered the market, as Plaintiffs allege it would have but for Defendants' alleged misconduct in 2012, rather than 2015, all or nearly all proposed Class members would have substituted generic Namenda IR for the brand and purchased the generic at lower prices than the brand. And further, but for the Hard Switch (as discussed further below), Namenda IR prescriptions (and hence, Namenda IR purchases by Class members) would have been higher at the time of generic entry and even assuming that there had been no earlier generic entry, proposed Class members who purchased Namenda XR would have purchased less XR and more IR and, with generic entry, would have switched to the lower priced generic Namenda IR. And with earlier generic entry, Class members who purchased only generic Namenda IR would have paid less for the generic they purchased.

ii. Forest's Acknowledgement of the Impact of Generic Entry on the Market for Memantine Hydrochloride Products

75. I have also reviewed evidence establishing that Forest understood and anticipated the effects that generic entry would have on prices, as discussed in the academic literature. This is an additional source of evidence that can be used to demonstrate the class-wide impact of the Defendants' alleged misconduct. I discuss this evidence in more detail below.

76. I have reviewed evidence in the form of Forest's acknowledgement that when AB-rated generic products enter the market, they typically do so at lower prices than their brand-name counterparts and also capture a significant share of the total unit sales for the drug. For example, at an investigational hearing in connection with the NYAG action, William Meury of Actavis testified:

Generally, direct generic competition has a significant impact sales of a branded product. [...] [G]enerally, when there's direct generic competition, whether it's a

Forest product or any product, there's an 80 to 90 percent reduction in sales. It's a fairly well-understood dynamic in the industry.<sup>146</sup>

Further, in its FY 2013 10-K, Forest stated that “[a]nother competitive challenge we face is from generic pharmaceutical manufacturers. Upon the expiration or loss of patent protection for a product, we may lose a major portion of sales of such product in a very short period.”<sup>147</sup> At a hearing in the related NYAG matter, Brent Saunders of Forest testified that the term “patent cliff” referred to the “time when generic competitors come in and generally take 90 percent or 99 percent of the market share from the brand.”<sup>148</sup>

77. In addition, the expected effects of AB-rated generic drug entry in the market for memantine hydrochloride products were also analyzed and acknowledged by Forest. For example, in an email to another Forest employee, Alex Kelly of Forest included an article from iStockAnalyst that included quotes from David Maris, BMO Capital Markets analyst, on the conversion to Namenda XR. The article states: “Namenda is set to go off patent in April 2015, and many generics (more than 10) are going to enter the market at that time. It is reasonable to expect that the price will drop by more than 90 percent.”<sup>149</sup> Further, in discussing the forced switch, the article noted that the Namenda XR Hard Switch strategy “results in higher overall healthcare costs as many of the patients who are given the new prescription will not return to the cheaper version when it becomes available.”<sup>150</sup>

78. During a January 21, 2014 Forest earnings call, Brent Saunders, CEO of Forest, stated: “I think, with respect to Namenda, what happens after the patent expiry, which is July of 2015, the product goes into – the franchise goes into decline.”<sup>151</sup> In a November

<sup>146</sup> William Meury Investigational Hearing, July 10, 2014 at 62:5-63:6.

<sup>147</sup> Forest Laboratories, Inc., SEC Form 10-K, fiscal year ended March 31, 2013 at p. 14. Forest also stated, “generic competitors can market a competing version of our product after the expiration or loss of our patent protection and charge much less for their product.”

<sup>148</sup> FRX-AT-01751083-1263 at 1086-1087.

<sup>149</sup> FRX-AT-04225926-28 at 26. Mr. Maris was further quoted as stating, “We expect that generic Namenda XR will result in an 80% drop in the Namenda XR/Namenda combo product franchise.” See FRX-AT-04225926-28 at 28.

<sup>150</sup> FRX-AT-04225926-28 at 27.

<sup>151</sup> FRX-AT-01775500-518 at 516. Similarly, at a January 7, 2014 Goldman Sachs Healthcare CEOs Unscripted Conference, Mr. Saunders of Forest stated: “clearly, when generic IRs enter the market in July or August of 2015, the Namenda franchise in and of itself will probably clearly not be a growth driver.” See FRX-AT-01782799-2812 at 2806.



2012 internal Forest analysis concerning the launch of a Namenda XR product, Forest assumes a “[p]eak erosion rate” of “IR branded by IR generics” of 95 percent to occur three months after generic entry.<sup>152</sup> An October 2013 Forest “Namenda IR & XR Conversion Plan” presentation forecasted the share of monthly days of therapy expected for branded and generic Namenda drugs under the “conventional” switch or “Soft Switch” strategy<sup>153</sup> for both an assumed loss of exclusivity for Namenda IR in January 2015 and July 2015.<sup>154</sup> In each of these scenarios, Forest projected that Namenda IR would rapidly lose the vast majority of its share of monthly days of therapy following its loss of exclusivity for Namenda IR.<sup>155</sup>

iii. Actual Sales of Namenda and Generic Memantine Hydrochloride  
Demonstrate Injury to Proposed Class Members

79. In addition to the academic literature cited above, as well as Defendant Forest’s own documents, data on the actual sales volumes and prices for Namenda (IR and XR) and generic memantine hydrochloride are another piece of evidence, common to all members of the proposed Class, with which to establish that all or nearly all proposed Class members were injured by Defendants’ alleged misconduct. To analyze the effect of generic entry in the market for memantine hydrochloride, I use data on brand-name Namenda (IR and XR) and generic memantine hydrochloride (immediate release) compiled by IMS.<sup>156</sup> Based on my review of IMS documents, IMS’s National Sales Perspectives database (“NSP”) “captures 100% of the total U.S. pharmaceutical market, measuring sales at actual transaction prices” and “monitors every major class of trade and channel of distribution for prescription pharmaceuticals, over-the-counter products and select, self-administered diagnostic products in the United States.”<sup>157</sup> Further, my review

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<sup>152</sup> FRX-AT-03713353-54.

<sup>153</sup> A “soft switch” or “conventional” strategy referred to Forest launching Namenda XR, but not withdrawing Namenda IR. See, for example, Forest 30(b)(6) Deposition at 107:19-108:7.

<sup>154</sup> FRX-AT-01641155 at slides 39, 41.

<sup>155</sup> FRX-AT-01641155 at slides 39, 41.

<sup>156</sup> IMS Health “[t]racks more than 80% of global pharmaceutical sales activity, 1.4+ million pharmaceutical products.” <http://www.imshealth.com/>.

<sup>157</sup> According to IMS, “[t]he IMS sales database is derived from the processing of more than 1.5 billion transactions each year. These transactions reflect both direct sales from approximately 100 pharmaceutical companies and indirect sales information from over 700 distribution centers. The universe of these direct and indirect sales are made to over 552 wholesalers, 223 drug and food chain warehouses, 5,793 non-

of documents and materials related to the IMS data indicate that the NSP data is considered reliable by economists and industry participants. According to IMS, NSP “is considered the industry standard for measuring pharmaceutical spending” and it is used by “a variety of healthcare policy setters and decision makers to monitor and assess national sales given its accuracy.”<sup>158</sup> Evidence indicates that Forest uses IMS data as well.<sup>159</sup>

80. I use the NSP data on dollar sales and extended units (“EU”)<sup>160</sup> of Namenda IR and Namenda XR and generic memantine hydrochloride products to compute sales volume measured as days of therapy (“DOT”)<sup>161</sup> and average price per day for Namenda IR and Namenda XR and generic memantine hydrochloride for each month between January 2011 and June 2017. For Namenda XR, the DOT is the same as EU because Namenda XR is taken once a day; for Namenda IR and generic memantine hydrochloride, the DOT is calculated as EU times 0.5 because Namenda IR and generic memantine hydrochloride are taken twice a day. Since proposed Class members are direct purchasers, I have restricted my analyses to the NSP data sales made by manufacturers Allergan, Actavis, Dr. Reddy’s, Sun, Macleods, Mylan, Lupin, Amneal, Unichem, Aurobindo, Alembic, Upsher-Smith, Ajanta, Wockhardt, and Torrent.<sup>162</sup> I have also excluded direct sales to government entities from my analyses. I reserve the right to revise my analyses of sales to direct purchasers if more information becomes available.

81. Below I discuss the effects of generic memantine hydrochloride entry on Namenda IR. Based on my analysis of the NSP direct sales data, six manufacturers (i.e., Actavis, Dr. Reddy’s, Sun, Mylan, Lupin, and Amneal) entered the market for generic

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federal hospitals and 334 federal government and non-government mail service pharmacies.” National Sales Perspectives Brief.

<sup>158</sup> National Sales Perspectives Brief.

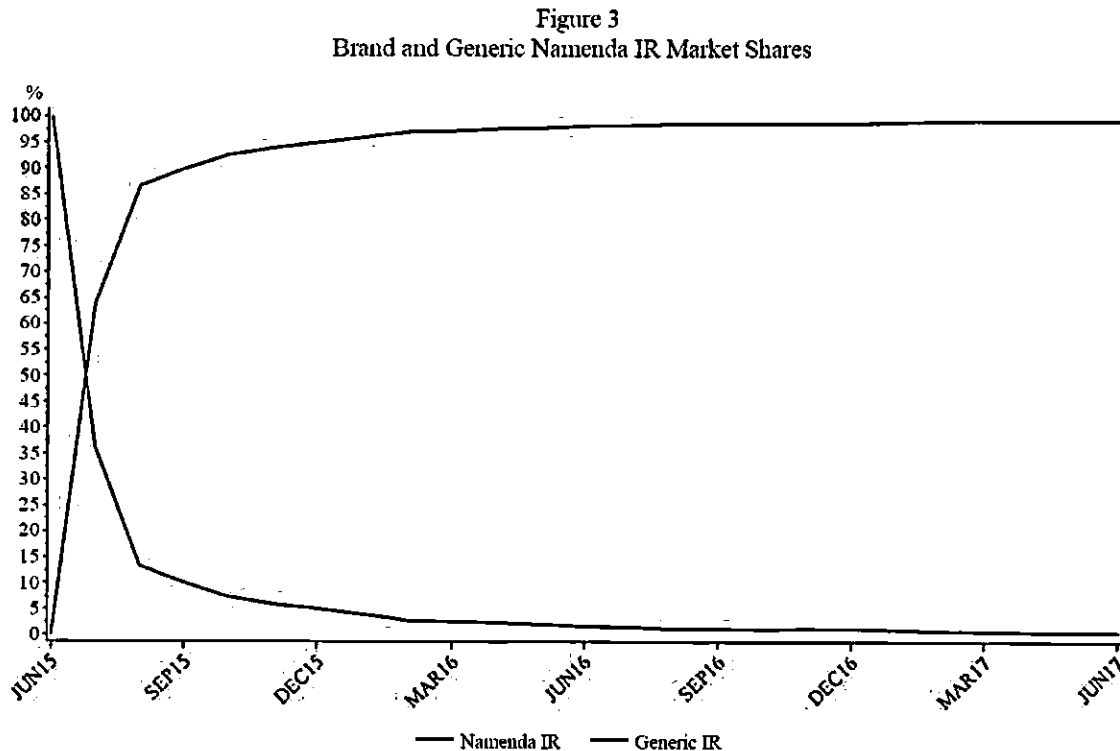
<sup>159</sup> Forest 30(b)(6) Deposition at 43:17-44:2.

<sup>160</sup> Extended units are a measure of the total quantity sold. IMS measures extended units in number of pills or millimeters of liquid depending on the form of the product. National Sales Perspectives Brief.

<sup>161</sup> Also referred to as days of treatment.

<sup>162</sup> There were re-packagers included in the manufacturer field of the IMS data, but I have removed them from my analyses. Therefore, the only manufacturers included in my analyses are the actual manufacturers of Namenda IR, Namenda XR and generic memantine hydrochloride. In the IMS data, the manufacturer for Namenda (IR and XR) is labelled as Allergan and the manufacturer for the authorized generic memantine hydrochloride is labelled as Actavis.

memantine hydrochloride in July 2015.<sup>163</sup> By September 2015, three months after generic entry, Forest had lost 89.9 percent of Namenda IR sales to generic manufacturers. Figure 3 below shows the sharp decline in Namenda IR's market share, measured as a percent of total Namenda IR DOT, experienced by Forest after generic entry.



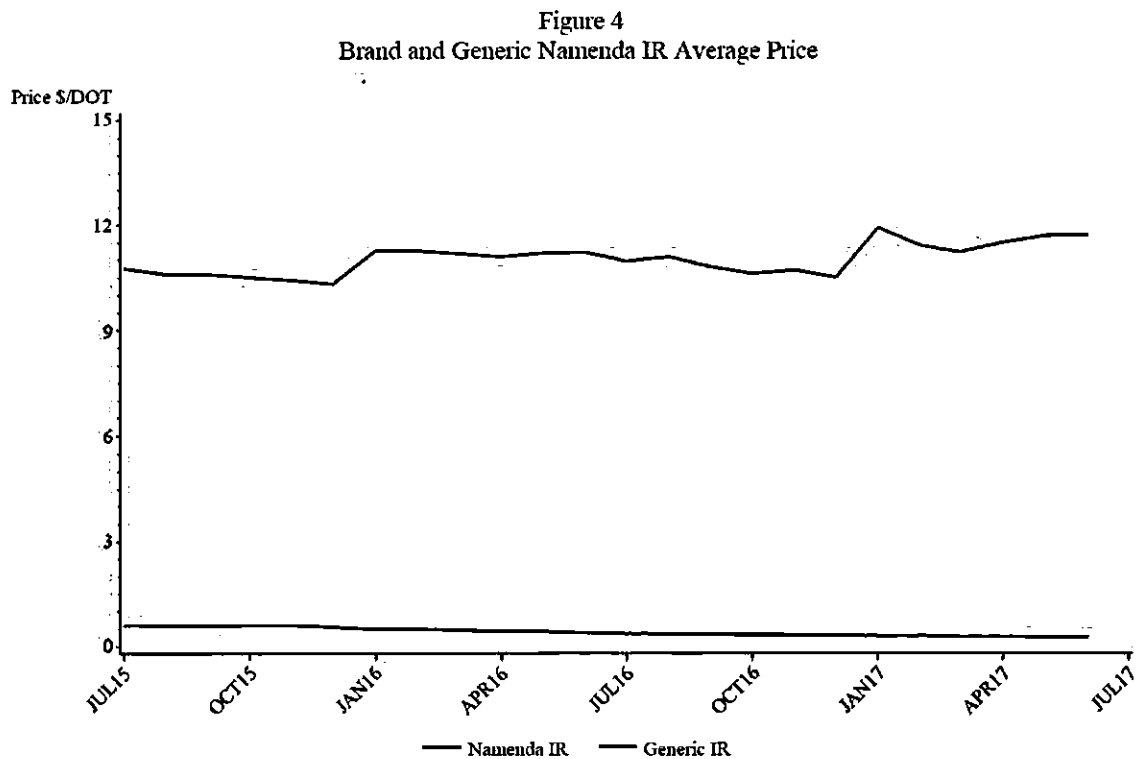
Source: NSP Data.

82. In July 2015, when the six manufacturers<sup>164</sup> began to sell generic memantine hydrochloride, the average price of generic memantine hydrochloride 5 mg products was 5.5 percent of the average price of branded Namenda IR 5 mg products, the average price of generic memantine hydrochloride 10 mg products was 5.3 percent of the average price of branded Namenda IR 10 mg products, and the average price of generic memantine hydrochloride titration 5-10 mg products was 5.4 percent of the average price of branded

<sup>163</sup> Actavis produced authorized generic memantine hydrochloride.

<sup>164</sup> There was no six-month period of exclusivity for any single manufacturer of generic Namenda IR. Rather, I understand that six generic manufacturers qualified to share generic exclusivity for the first six months following patent expiration. Further, Forest's agreements with generic manufacturers allowed each manufacturer to enter if any other generic Namenda IR product came onto the market.

Namenda IR titration 5-10 mg products. Figure 4 below shows the difference between the average generic memantine hydrochloride price and the average price of Namenda IR over time.



Source: NSP Data.

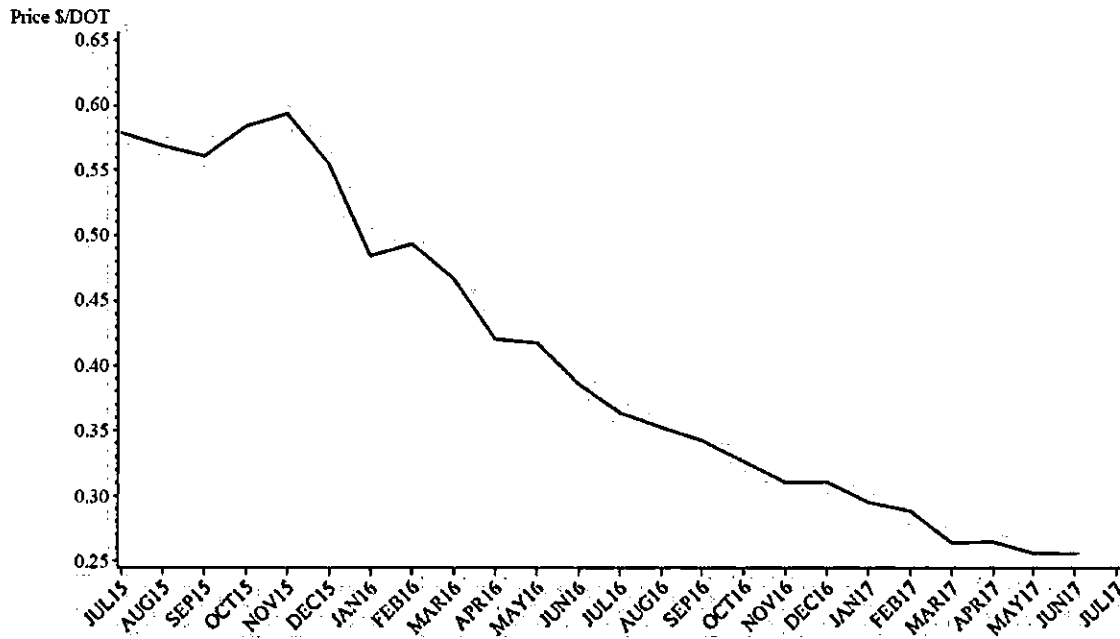
83. My analysis of the NSP data on sales and prices for Namenda IR and generic memantine hydrochloride confirm the findings from the economics literature analyzing the effects of generic competition on prices and market shares for brand-name and generic drugs. That is, the nearly-95 percent price discount of generic memantine hydrochloride relative to Namenda IR, along with the rapid substitution of generic memantine hydrochloride for branded Namenda IR, is consistent with the literature describing the effects of generic entry on prices and sales in pharmaceutical markets.

84. The rapid substitution of lower-priced generic memantine hydrochloride for the higher-priced Namenda IR that occurred after generic entry is evidence, common to the proposed Class as a whole, that if generic entry had occurred earlier, proposed Class

members, to meet market demand, would have purchased generic memantine hydrochloride in place of branded Namenda IR, and these purchases would have been made at lower prices. My analysis of the NSP data on Namenda IR and generic memantine hydrochloride is one piece of common evidence demonstrating that proposed Class members were injured as a result of the alleged unlawful delay in market entry of generic memantine hydrochloride. This same evidence also shows that, had branded Namenda IR prescriptions been higher at the time of generic entry (whenever it occurred) but for the Hard Switch (which they would have been, as discussed below), then Class members were injured as a result of the Hard Switch. This is because, had the base of branded Namenda IR prescriptions been higher at the time of generic entry, the rapid substitution of generic Namenda IR for the brand would have affected a larger base of IR prescriptions and, consequently, Class members would have obtained savings by purchasing generic Namenda IR at prices below either branded Namenda IR or branded Namenda XR.

85. Further, as shown in Figure 5 below, the price of generic Namenda IR declined over time following its initial launch in July 2015, a typical pattern seen with generic competition. Therefore, the price paid for generic Namenda IR by proposed Class members in the actual world following the launch of generic Namenda IR would have been lower in the but-for world had there been earlier generic entry. In other words, a proposed Class member who purchased generic Namenda IR at a price of \$0.58 per tablet in July 2015, would have purchased the generic at a price *below* \$0.58 in July 2015 had generic competition started in 2012, rather than July 2015, because had generic competition started in 2012, the decline in generic prices that actually occurred after July 2015 would have occurred much earlier. Hence the purchase the proposed Class member actually made at a price of \$0.58 in July 2015 would have been made at a lower price. The difference in price – the difference between \$0.58 actually paid in July 2015 or thereafter and the lower price that would have been paid with earlier generic entry – constitutes another category of damages (what I refer to as “G-G damages”), which I discuss in greater detail below. In sum, assuming generic competition was unlawfully delayed, all or nearly all Class members suffered injury in the form of an overcharge.

Figure 5  
Generic Namenda IR Average Price



Source: NSP Data.

#### *D. Anticompetitive Impact Under the No Hard Switch But-For World*

86. As I discuss elsewhere, I understand that Plaintiffs allege that Defendant Forest engaged in a number of actions designed to thwart the effect of generic competition on Namenda prices by introducing and attempting to maximize conversion from Namenda IR to Namenda XR. As I discuss below, Forest's introduction of Namenda XR was intended to stall the "patent cliff" that arises from generic competition and, as described by one Namenda executive, turn it into a "steady decline."<sup>165</sup> Because Namenda XR is listed separately in the Orange Book, by converting patients to Namenda XR, Forest could prevent generic substitution because generic Namenda IR would not be AB-rated to, and therefore not substitutable for, branded Namenda XR. However, Forest soon realized that a *voluntary* conversion to Namenda XR would not result in enough Namenda patients switching from Namenda IR. Forest consequently designed a further

<sup>165</sup> FRX-AT-01782799-2812 at 2803, 2806.

plan to force Namenda patients onto Namenda XR by publicly announcing the intention to withdraw, and then withdrawing, Namenda IR from the marketplace months in advance of generic entry. By converting more Namenda IR patients to Namenda XR as a result of announcing the withdrawal Namenda IR, even though it was not able to ultimately complete its entire strategy because of a Court order, Forest was in fact able to significantly impede generic substitution and the loss of market share that accompanied it, as I discuss in more detail below.

i. Summary of Earlier Findings Regarding Generic Entry

87. As I discussed above, the entry of AB-rated generics into the memantine hydrochloride market in July 2015 resulted in a nearly-instantaneous and nearly-complete elimination of branded Namenda IR sales. The effect of generic entry is well-documented in the economic literature and, as noted above, was both understood and anticipated by Forest. As I discuss elsewhere, within six months of generic entry, Forest had lost 96.5 percent of Namenda IR sales. However, as I discuss in more detail below, Forest retained significant sales of Namenda, because its “Hard Switch” strategy had allowed it to convert more than 50 percent of Namenda patients (measured as DOT) to Namenda XR, far more than the approximately 30 percent that its own planning indicated would be possible in the absence of a hard switch.

ii. Impact of Forest’s Hard Switch Strategy for Namenda XR

88. As a result of the vastly expanded market share captured by Namenda XR following Forest’s pursuit of the Hard Switch strategy, proposed Class members paid more for the memantine hydrochloride they purchased than they otherwise would have. This is demonstrated by the nearly-complete conversion to generic versions of Namenda IR (with the accompanying decline in prices) along with the much slower generic penetration of Namenda XR (i.e., the much slower rate at which prescriptions for Namenda XR, having already been switched from Namenda IR or having first begun as XR, switch to generic Namenda IR).<sup>166</sup> In other words, but for the Hard Switch, there

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<sup>166</sup> As discussed below, XR prescriptions fall after generic IR is available as patients transition off of XR due to death or cessation of treatment, and are in effect replaced by new patients who start on the (now available) lower priced generic IR.

would have been significantly fewer Namenda XR prescriptions and, at the time of generic Namenda IR entry, significantly more Namenda IR prescriptions, and it is the branded Namenda IR prescriptions that form the “base” of prescriptions that generic IR would quickly take over (whenever such generic entry occurred). By shrinking that base via the Hard Switch, Forest suppressed generic competition and caused proposed Class members to be overcharged because instead of purchasing generic Namenda IR at low prices, they were forced to buy branded Namenda XR at higher prices.

a. Forest’s Decision to Pursue the Hard Switch Strategy

89. As I previously discussed, Forest announced that Namenda XR became available throughout the U.S. on June 13, 2013.<sup>167</sup> By October 18, 2013, Forest had determined that it would implement the Hard Switch strategy.<sup>168</sup> Then, on February 14, 2014, Forest issued a press release announcing that it planned to discontinue sales of its Namenda IR tablets as of August 15, 2014, noting further that Namenda XR would still be available to consumers.<sup>169</sup> These facts are consistent with Plaintiffs’ allegations that as a result of Forest’s dissatisfaction with the extent of conversion to Namenda XR several months after its launch, Forest began to consider an option where it would discontinue or dramatically restrict the supply of Namenda IR several months before the availability of generic memantine hydrochloride in order to accomplish a “forced switch” whereby physicians and patients would have little choice but to switch to Namenda XR.<sup>170</sup>

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<sup>167</sup> Forest Laboratories, Inc., “Forest Announces U.S. Availability of New Once-Daily NAMENDA XR,” *BusinessWire*, June 13, 2013. Available at <http://www.businesswire.com/news/home/20130613005088/en/Forest-Announces-U.S.-Availability-New-Once-Daily-NAMENDA>; Complaint at ¶149.

<sup>168</sup> FRX-AT-01779417-19 at 17 (October 18, 2013 email from Gary Simorski, “Forest has made the decision to discontinue sales of Namenda IR and transition all patients to Namenda XR.”).

<sup>169</sup> Forest Laboratories, Inc., “Forest Laboratories to Discontinue NAMENDA® Tablets, Focus on Once-Daily NAMENDA XR®,” *BusinessWire*, February 14, 2014. Available at <http://www.businesswire.com/news/home/20140214005829/en/Forest-Laboratories-Discontinue-NAMENDA%C2%AE-Tablets-Focus-Once-Daily>; Complaint at ¶174. Forest also notified the FDA of its intention to discontinue sales of Namenda IR as of August 15, 2014, on February 14, 2014. See FRX-AT-04519466-67; FRX-AT-01821687-89; Complaint at ¶174. In addition, on February 18, 2014, Forest informed the Center for Medicare and Medicaid Services (“CMS”) of its intention to discontinue sales of Namenda IR as of August 15, 2014, noting that CMS ought to remove Namenda IR from its 2015 Formulary Reference File (“FRF”). See FRX-AT-04380946-47; Complaint at ¶179.

<sup>170</sup> Complaint at ¶¶158-173.



Internal documents produced by Forest confirm the company's formation and implementation of this strategy.

90. For example, in a June 2013 working draft of a Forest presentation titled "Namenda IR to XR Conversion Project," Forest evaluated three Namenda XR launch strategies: a "Conventional" (Soft Switch), "Withdrawal" (Hard Switch), and "Limited Distribution."<sup>171</sup> In this presentation, Forest noted that the decision of which strategy to pursue was "to be based on degree of success in converting Namenda IR to Namenda XR."<sup>172</sup> Forest further noted that the "[k]ey variables in [the] evaluation of success" of this product launch were "IR to XR conversion and date of IR LOE."<sup>173</sup> With respect to the question of "IR to XR conversion success," Forest indicated that one factor in determining this success was whether or not Namenda XR was tracking against its goal in the first year following its launch.<sup>174</sup>

91. Evidence I have reviewed indicates that Namenda XR had not been meeting its goals for converting Namenda IR to Namenda XR in the months immediately following its launch. For example, in an August 9, 2013 "Namenda XR Weekly Performance Tracker," Forest reported that the "[t]otal weekly conversion for Namenda XR is 2.80% vs. budget of 5.41%."<sup>175</sup> In a September 12, 2013 memo from the Namenda XR brand team to Namenda XR representatives, it was noted that, despite an upturn in conversion over the last few weeks, Forest "need[ed] to accelerate [its] efforts in order to meet [its] FY14 goal of 20%."<sup>176</sup> On October 30, 2013, David Okimoto of Forest emailed a colleague regarding the "Namenda conversion," noting that Forest's market research department was "concerned that XR business [was] not picking up as much as expected

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<sup>171</sup> FRX-AT-01775302-319. Under the Limited Distribution strategy, "[f]or commercial, Medicare Part D, Medicaid FFS, Managed Medicaid, and cash patients, Namenda IR available solely through mail order distribution." Further, "[f]or FSS-covered patients (VA) and PHS-covered patients (340B program), Namenda IR would continue to be distributed via VA and 340B clinics and retail pharmacies." See FRX-AT-01775302-319 at 304.

<sup>172</sup> FRX-AT-01775302-319 at 304.

<sup>173</sup> FRX-AT-01775302-319 at 306.

<sup>174</sup> FRX-AT-01775302-319 at 306. The other factor concerned a question of near-term revenue versus overall net present value.

<sup>175</sup> FRX-AT-01593279-282 at 280. In response to these results, William Meury of Forest stated that the company was "making progress but it's slow. At the current pace XR will represent 15 percent of the total line. Formulary coverage is good and patient satisfaction doesn't appear to be a problem, which means it's on us." See FRX-AT-01593279-282 at 279.

<sup>176</sup> FRX-AT-03860760.

in [long-term care].”<sup>177</sup> A December 20, 2013 “Namenda XR Recent Trend Analysis” presentation stated that in “October 2013, a sharp decline was seen in Namenda XR NRx conversion rates driven by [long-term care].”<sup>178</sup> A December 2013 memo from the Namenda XR brand team to Namenda XR representatives noted:

At the launch meeting, we set a goal to reach a 12% conversion rate of total prescriptions by mid- December. [...] Today our total RX conversion rate is 11.3% and so we are appearing to be on track. However, a telltale indicator of total prescriptions is new prescriptions, and the trend for new prescriptions over the past few weeks is starting to slow and flatten. This is concerning.<sup>179</sup>

Following an analysis of “Namenda XR Conversion by Channel” from late January, several Forest employees emailed each other discussing the results.<sup>180</sup> Troy Sheldon of Forest noted that conversion rates among “GPOs are still lagging significantly,” to which Mark Devlin of Forest responded by noting that “there are some gains since 1/1 but not at the magnitude I would’ve expected for any customer...retail or LTC.”<sup>181</sup> Mr. Sheldon then responded that “[o]verall the performance is underwhelming.”<sup>182</sup>

92. The evidence cited above indicates that conversion from Namenda IR to Namenda XR was not meeting Forest’s expectations under the Soft Switch strategy in the months following the launch of Namenda XR, which, as I previously discussed, was the primary factor that Forest used to determine whether to pursue a Hard Switch strategy.<sup>183</sup> Evidence indicates that Forest anticipated that a Hard Switch strategy would have a

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<sup>177</sup> FRX-AT-01806018. Regarding this concern, Mr. Okimoto stated that “it appears that the MHA performance (more independent pharmacies) are converting at a much slower pace and that we may be better off refocusing our messages to educate these pharmacies so that we can move things in the right direction.” See FRX-AT-01806018.

<sup>178</sup> FRX-AT-01608854 at slide 2. I have noted that this presentation indicates that part of this sharp decline was due to an “IMS projection issue.” See FRX-AT-01608854 at slide 2. However, this presentation shows NRxs of Namenda XR declining beginning in late September 2013 after accounting for this correction. See FRX-AT-01608854 at slide 5.

<sup>179</sup> FRX-AT-01775242. Forest further discussed ways in which Namenda XR representatives could “turn this trend around” to enable Forest to reach its December goal. To incentivize representatives to reach this goal, Forest re-structured their “Incentive Compensation Plan” so that representatives would be “paid only on Namenda XR prescriptions,” and that they would “no longer [be] paid on Namenda prescriptions.” Further, representatives were to receive a \$50 bonus for “every new decile 3-10 prescriber [they] add[ed] in the month of December.” See FRX-AT-01775242.

<sup>180</sup> FRX-AT-03686632-33 at 32.

<sup>181</sup> FRX-AT-03686632-33 at 32.

<sup>182</sup> FRX-AT-03686632-33 at 32.

<sup>183</sup> FRX-AT-01775302-319 at 304, 306.

significant impact on the rate of conversion to Namenda XR beginning from the time it was communicated to the market.<sup>184</sup> Below I discuss evidence demonstrating that Forest understood the impact that announcing and pursuing the Hard Switch strategy would have in reducing the level of competition from generic memantine hydrochloride products.

b. Forest Acknowledged that the Hard Switch Strategy Would Reduce the Level of Competition from Generic Memantine Hydrochloride Products

93. Above, I discussed the peer-reviewed economic research that demonstrates that when AB-rated generic products enter the market, they typically do so at lower prices than their brand name counterparts and also capture a significant share of the total unit sales for the drug (brand plus generic). I further discussed common evidence demonstrating that Forest was aware of the effect that generic entry had on sales of branded drugs and expected that generic competition would have this same effect on Namenda IR. Additional common evidence I have reviewed demonstrates that Forest understood the impact that announcing and pursuing the Hard Switch strategy would have in reducing the level of competition from generic memantine hydrochloride products. I discuss this common evidence in greater detail below.

94. For example, at a Goldman Sachs Healthcare CEOs Unscripted Conference held on January 7, 2014, Brent Saunders of Forest was asked about the company's strategy for sales growth to "offset what's expected to go down [...] after generics [enter] the market" for Namenda.<sup>185</sup> Mr. Saunders responded that Forest was "actively considering and debating a hard switch" strategy, noting further: "What we're trying to do is put up barriers or obstacles to go from a cliff to a steady decline, right, a steady managed decline over four or five years versus in three months a \$1.6 billion product is \$200 million."<sup>186</sup>

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<sup>184</sup> For example, in an October 2013 series of emails among Forest employees discussing an "[u]pdated Namenda model with production forecast," Lei Meng of Forest forecasted "IR to XR conversion accelerating two-fold following the announcement of withdrawal." See FRX-AT-03724244-47 at 44.

<sup>185</sup> FRX-AT-01782799-2812 at 2805.

<sup>186</sup> FRX-AT-01782799-2812 at 2806. Regarding Forest's strategy, Mr. Saunders also stated that "generic Namenda IR is going to take a lot of the new starts, but it's about maintaining the base that you have now and fighting for some of those new starts with the once-a-day convenience or the combo pill." See FRX-AT-01782799-2812 at 2807. He also stated: "If you kind of look at the timing of IR, IR will go generic in July of 2015. And so the sweet spot for a switch would be in the fall, and so that's kind of how we're thinking about it." See FRX-AT-01782799-2812 at 2806. In a December 2014 Declaration in the related

Similarly, at a January 21, 2014 Forest earnings call, Mr. Saunders of Forest stated the following regarding Namenda XR: “I think our view is that what we’re trying to do is make a cliff disappear and rather than have a long – a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users.”<sup>187</sup> In a May 2013 speech concerning the launch of Namenda XR, Mark Devlin of Forest stated:

[T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.<sup>188</sup>

Mr. Devlin added that the “better job we do moving business from IR to XR, the more Forest revenue we hopefully shelter from generic threats down the road.”<sup>189</sup> An internal Forest “Namenda Franchise” presentation regarding the transition to Namenda XR stated that “[s]ales for XR are expected to total \$1.4 billion FY16 due to pediatric exclusivity and the XR conversion (XR transition) versus \$768MM in a Namenda IR only situation (conventional).”<sup>190</sup> A December 2013 Forest “Namenda Transition” presentation stated that the transition from Namenda IR to Namenda XR would “[p]reserve 75% of sales and income over four years (FY15-18),” and also “[p]roduce \$1.5 billion in incremental operating income.”<sup>191</sup>

95. An October 2013 Forest “Namenda IR & XR Conversion Plan” presentation forecasted the share of monthly days of therapy branded and generic Namenda drugs under the Soft Switch and Hard Switch strategies for both an assumed loss of exclusivity

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NYAG matter, William Meury of Actavis stated that “[s]lowing Namenda XR’s decline would also allow Forest to save jobs that might otherwise be lost as a result of the ‘patent cliff.’” See FRX-AT-01747623-634 at 627.

<sup>187</sup> FRX-AT-01775500-518 at 516. Mr. Saunders further stated the Hard Switch strategy created “an obstacle that will allow us to, I think, again, go into a slow decline versus a complete cliff.” See FRX-AT-01775500-518 at 516.

<sup>188</sup> FRX-AT-01775214-17 at 14. Mr. Devlin further stated that, given this, “time is of the essence here... we cannot afford a slow build of market access... our sales organization needs managed care access now...and by that I mean as close as possible to the early days of launch, plans need to be covering XR as a preferred brand. If we expect to convert rapidly... which we do...we need open access by July 1, 2013 and that has been our focus with the managed care team the last 6 months.” See FRX-AT-01775214-17 at 14.

<sup>189</sup> FRX-AT-01775214-17 at 17.

<sup>190</sup> FRX-AT-01720911-12.

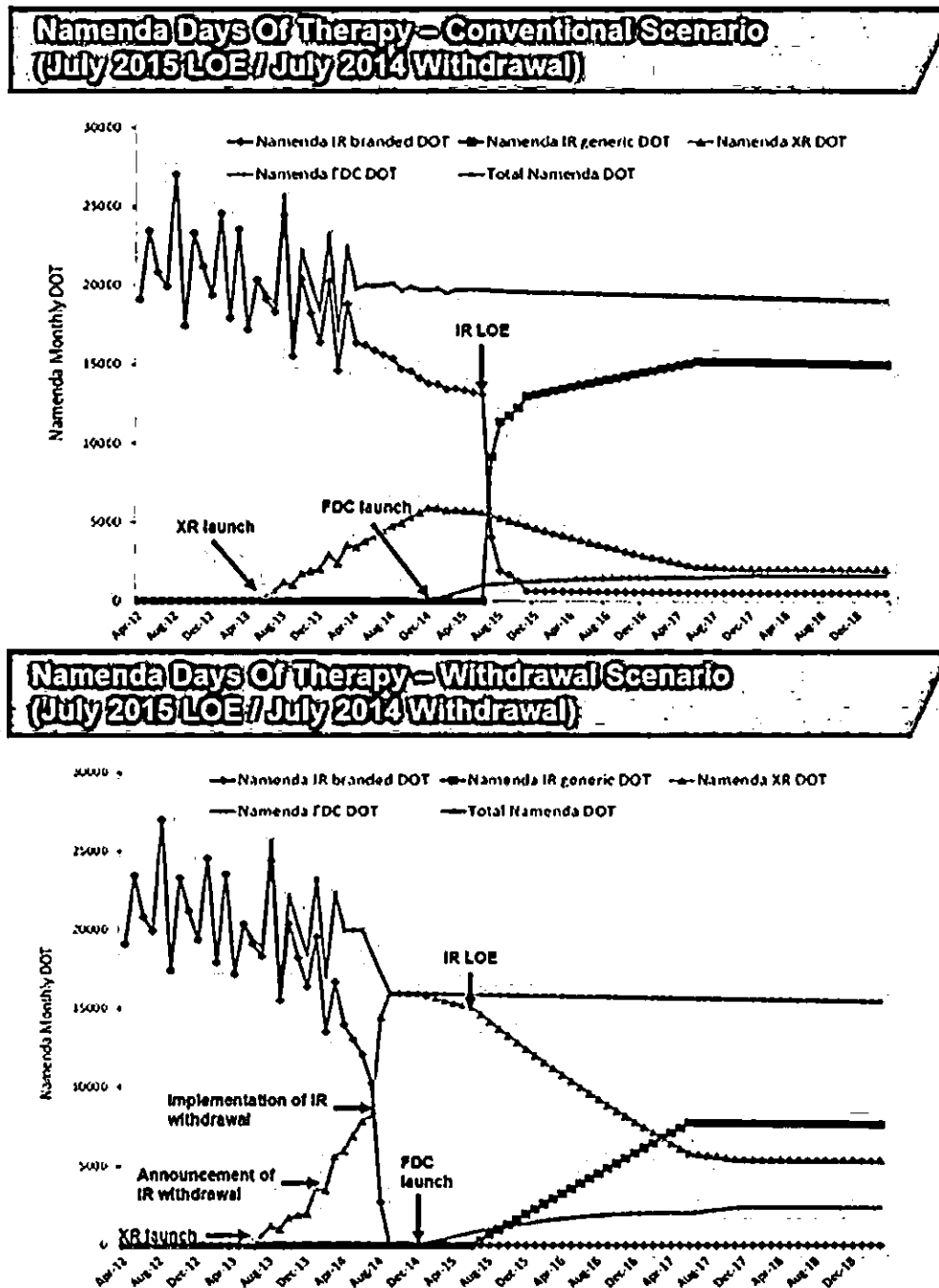
<sup>191</sup> FRX-AT-01781368-381 at 372.

for Namenda IR in January 2015 and July 2015.<sup>192</sup> Figure 6 below is a copy of these Soft Switch and Hard Switch strategy forecasts under an assumed loss of Namenda IR exclusivity in July 2015. As shown, under the Soft Switch strategy, Forest projected that generic Namenda IR products would very quickly capture a majority of the market for memantine hydrochloride products (approximately 8,000 days of therapy in July 2015 out of 19,687) following Forest's loss of exclusivity, eventually leveling off at a peak of approximately 14,000 days of therapy. However, as shown below, under the Hard Switch strategy, Forest instead projected that generic Namenda IR products would enter the market at a much slower growth rate, ultimately leveling off at a peak share of the market that was approximately half of the share that Forest projected generic Namenda IR products would achieve if Forest pursued just the Soft Switch strategy. Put another way, Forest projected that moving to a Hard Switch strategy from a Soft Switch would cut generic Namenda IR sales roughly in half. Further, as shown below, Forest projected that Namenda XR's share of the memantine hydrochloride market would be significantly higher under the Hard Switch strategy versus the Soft Switch strategy.

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<sup>192</sup> FRX-AT-01641155 at slides 38-41.

Figure 6  
Forest Namenda Forecasts



Source: FRX-AT-01641155 at slides 40-41.

96. Evidence I have reviewed demonstrates that Forest took drastic steps in order to ensure this reduced level of competition from generic manufacturers of memantine hydrochloride products through its planned implementation of the Hard Switch strategy.

For example, evidence I have reviewed indicates that it was exceedingly rare, if not unprecedented, for a drug manufacturer to withdraw a first-generation drug from the market prior to the loss of its patent exclusivity when there were no other drugs in the same therapeutic class (except for instances where doing so was mandated by the FDA).<sup>193</sup> Further, evidence I have reviewed indicates that Forest expected that its decision to withdraw Namenda IR from the market prior to its loss of exclusivity in order to transition the market to Namenda XR would have resulted in lower profits in the short term.<sup>194</sup> Given this, it is unlikely that Forest would have pursued the Hard Switch strategy if it didn't expect that doing so would have reduced competition from generic memantine hydrochloride products to a degree that would have allowed it to earn greater profits in the long-run than if they hadn't chosen to pursue this strategy.

97. The evidence cited above demonstrates that Forest was aware of the impact that pursuing the Hard Switch strategy would have in reducing the level of competition from generic memantine hydrochloride products. Particularly, this evidence demonstrates that Forest was aware that when AB-rated generic products (such as generic Namenda IR) enter the market, they typically do so at lower prices than their brand name counterparts and also quickly capture a significant share of the total unit sales for the drug.

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<sup>193</sup> For example, in a September 2012 email among Forest employees regarding past instances where manufacturers utilized a "follow-on strategy" to launch a new drug, Thomas Nee of Forest reported that it was "unable to find any analogues of product conversions in the recent 5 years where the first product was pulled from the market, other than FDA mandated reformulations." See FRX-AT-01775151-161 at 153. In a Forest presentation "[e]valuating withdrawal of Namenda from U.S. market," it was noted that such a strategy was "[u]nprecedented – would be operating in uncharted [sic] territory." See FRX-AT-01606419 at slide 3. This presentation further noted: "To date – it has been in response to FDA requests that products have been withdrawn (e.g., Asacol) or distributed in a limited manner (Qsymia)." See FRX-AT-01606419 at slide 3.

<sup>194</sup> For example, in an October 2013 "Namenda IR & XR Conversion Plan," Forest analyzed the FY2015 impact on net sales under a number of Namenda IR withdrawal scenarios. Under the scenario that assumed a withdrawal notification in January 2014 and a loss of exclusivity in July 2015, Forest forecasted a loss of \$237 million in FY2015 under the Hard Switch strategy as compared to the Soft Switch strategy. See FRX-AT-01780928-966 at 960. In a Forest presentation titled "Namenda Franchise," Forest stated that it is "[c]ommitted to [m]aximizing the Namenda [f]ranchise – [i]nvestment [g]reater [t]han \$400 [m]illion," adding that "[s]ignificant investment will be required to support discontinuation of Namenda IR and ensuring patients switch to Namenda [X]R." See FRX-AT-03732735-742 at 737. See, also, FRX-AT-01751083-1263 at 1181-1183; FRX-AT-01751083-1263 at 1126-1129; FRX-AT-01730505-0664 at 0561-0562; FRX-AT-01828875-892 at 877.



c. Forest's Efforts to Market the Hard Switch to Physicians, Caregivers, and Pharmacies Played a Key Role in the Transition to Namenda XR.

98. In an effort to ensure the success of its Hard Switch strategy for Namenda XR, Forest expended considerable amounts of capital and resources to inform the public of its plan to pursue this strategy. As noted in a June 2013 working draft of a Forest "Namenda IR to XR Conversion Project," one of the "[k]ey considerations" of this strategy was the "[p]otential negative reaction by key stakeholders and customers," noting further that "Alzheimer's patients [are] viewed as highly vulnerable."<sup>195</sup> In light of this key consideration, Forest noted the "[n]eed to over-communicate to all stakeholders and provide support throughout the process."<sup>196</sup> I discuss in more detail below evidence demonstrating Forest's extensive efforts to "over-communicate" with key stakeholders (such as physicians, caregivers, and pharmacies) and customers regarding its planned implementation of the Hard Switch to Namenda IR.

99. For example, an April 2014 Forest memo analyzed "initiatives that will help [Forest] continue to drive conversion to XR" leading up to the planned withdrawal of Namenda IR in August 2014.<sup>197</sup> The first such initiative noted was that the "discontinuation communications continue to go out to physicians, caregivers, and pharmacies weekly (caregivers) and monthly (physicians)."<sup>198</sup> This memo noted further that as it got "closer to August, the communications will become more targeted" depending on the recipient.<sup>199</sup> Also discussed was "new branding that will roll out in

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<sup>195</sup> FRX-AT-04254209-228 at 214.

<sup>196</sup> FRX-AT-04254209-228 at 214. See, also, FRX-AT-01781368-381 at 372. In a February 2014 email conversation among Forest employees regarding the communication efforts with respect to the Hard Switch strategy, Brian Ellis of Forest stated that "it is going to be vital that we over communicate this change." See FRX-AT-03565770-73 at 70. See, also, FRX-AT-03793759-765 at 762; FRX-AT-01874319; FRX-AT-01893031-041 at 031-032.

<sup>197</sup> FRX-AT-04038657-58.

<sup>198</sup> FRX-AT-04038657-58 at 57. See, also, FRX-AT-01893676-78 at 77. This memo specifically noted "the Caremark physician and patient letters went out and United will be mailing theirs this week so that should help to continue to drive conversion." See FRX-AT-04038657-58 at 57. Forest also noted that it was "looking into radio and newspaper ads as well that [it] will likely roll out in June." See FRX-AT-04038657-58 at 58.

<sup>199</sup> FRX-AT-04038657-58 at 58. See, also, FRX-AT-01893676-78 at 77. In this memo, Forest discussed three different categories of recipients, and discussed how specifically to communicate with those recipients. For example, for one group, it was suggested that the recipients "may have lack of awareness so we would want to have call center reach out to them." For another group of recipients, Forest noted that they "should get continued communication so they continue to prescribe Namenda XR as patients return to their offices." See FRX-AT-04038657-58 at 58.



about a week that will speak very specifically to the conversion – switching from twice a day to once a day. A mailing to physicians and a rep detailing piece will be first, followed by emails to both physicians and caregivers.”<sup>200</sup> At a May 2014 “POA Managers Meeting,” Will Kane of Forest discussed the company’s concerted efforts to transition patients to Namenda XR through a variety of communications techniques, noting that Forest “deployed a comprehensive communications effort across stakeholders to achieve this goal, and we continue to add new tactics.”<sup>201</sup> A Forest “Namenda Withdrawal Sales Force Training” presentation stated: “We are communicating the withdrawal immediately and for the next six months,” noting the following strategy:

- Physicians will receive first communication this week
  - Over 150,000 physicians will receive letters, emails, and online messages
- Pharmacists will receive first communication this week
  - We will reach over 200,000 pharmacists with retail chain driven announcements, emails and letters from Forest
- LTC Professionals will receive first communication this week
  - Emails and letters to 170,000 LTC attending physicians, consultant pharmacists, Directors of Nursing and Medical Directors
  - Letters to LTCPPs, GPOs, SNF chains, & independent LTC pharmacies
- Caregivers will receive first communication next week
  - 1.7MM caregivers will receive a combination of emails, letters, and pharmacy messages
- Health Plans
  - All health plans will receive letters on the withdrawal and will be provided with form letters to disseminate to their physicians and patients<sup>202</sup>

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<sup>200</sup> FRX-AT-04038657-58 at 58.

<sup>201</sup> FRX-AT-03793847-856 at 849. Mr. Kane noted that, at the time, Forest’s “comprehensive communications efforts” had reached 150,000 MDs, 200,000 pharmacists, and 1,500,000 caregivers. See FRX-AT-03793847-856 at 849. “POA” refers to “plan of action.” See, Forest 30(b)(6) Deposition, at 198:2-5.

<sup>202</sup> FRX-AT-03872025-066 at 030.

100. In addition, I have reviewed evidence demonstrating that Forest expended significant amounts of capital in connection with its efforts to communicate its planned discontinuation of Namenda IR with key stakeholders. For example, in a December 2014 Declaration in the related NYAG matter, William Meury of Actavis stated that Forest “invested over \$120 million in creating and training a salesforce to educate physicians, caregivers and pharmacists about Namenda XR.”<sup>203</sup> In a February 2014 email to Philip Burchard (Merz), David Solomon of Forest stated, “As you know, Forest has made a tremendous investment in Namenda lifecycle, and is continuing to invest heavily behind the IR-to-XR switch. This investment of over \$425 million, for which Forest has taken all the up-front cost and risk, will provide substantial benefit to both our companies.”<sup>204</sup> A February 24, 2014 “Namenda Franchise” presentation stated that “[s]ignificant investment will be required to support discontinuation of Namenda IR and ensuring patients switch to Namenda [X]R.”<sup>205</sup>

101. Further, in order to transition as many patients as possible to Namenda XR prior to Forest’s loss of patent exclusivity on Namenda IR, and to afford patients with as smooth of a transition to Namenda XR as possible, Forest publicly announced its Hard Switch strategy six months prior to its planned effective date. According to Forest, this lead time was important as it afforded it a sufficient amount of time to communicate with key stakeholders and customers to provide for a transition to Namenda XR with as little disruption to patient care as possible. For example, in an October 2013 “Namenda IR & XR Conversion Plan,” Forest stated that one of the “[e]lements of a successful transition” to Namenda XR is to “[c]ommunicate early and often to all relevant audiences.”<sup>206</sup> This same presentation noted that “87% of pharmacists would want to tell Namenda patients when the[y] come in for their prescriptions that a change was going to happen,” adding:

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<sup>203</sup> FRX-AT-01747623-634 at 625. Mr. Meury also stated that in “deciding whether to discontinue Namenda IR tablets, Forest commissioned multiple surveys conducted by third-party health care market research firms over a period of three months in the Fall 2013, at a cost of more than \$270,000.” See FRX-AT-01747623-634 at 627.

<sup>204</sup> FRX-AT-01621653-654 at 653.

<sup>205</sup> FRX-AT-01621655 at slide 3.

<sup>206</sup> FRX-AT-01780928-966 at 943. Included in this communication plan was “MDs awareness” which would be achieved through training by the Forest “field force;” the enlistment of pharmacists “to mitigate disruption at the pharmacy;” the closing of formulary coverage gaps “so that patients don’t pay more for IR than XR;” and the management of production requirements. See FRX-AT-01780928-966 at 943.

“This would suggest the 3-6 month advance notice would be helpful for pharmacists to ensure Namenda patients are informed when the[y] come into refill their Rx’s.”<sup>207</sup> A Forest “Namenda Withdrawal Sales Force Training” presentation stated that the “transition will occur over the next six months,” as it “is important that health care providers work with patients and their caregivers to transition to Namenda XR as soon as possible to facilitate continuity of care.”<sup>208</sup>

102. Evidence I have reviewed indicates that Forest communicated its intention to withdraw Namenda IR to managed care entities to influence the decision to add Namenda XR to their formularies. For example, in an October 2013 email to colleagues, Forest’s National Account Manager, Jerry Hester, indicated that he informed Optum<sup>209</sup> that Forest would be withdrawing Namenda IR, and he informed others at Forest that Optum “said they would add [Namenda XR to its formulary] on 1/1/2014 and assist us with communicating the IR withdraw[a]l from market to the membership.”<sup>210</sup> This demonstrates that, while the official public announcement was not made until February 14, 2014, Forest had been informing managed care plans about the decision regarding the Hard Switch strategy earlier as part of its effort to increase formulary coverage for Namenda XR.

103. The evidence discussed above demonstrates the importance that broad and extensive communication with key stakeholders and customers regarding the Hard Switch strategy had in driving conversion from Namenda IR to Namenda XR prior to Forest’s loss of exclusivity for Namenda IR. Despite the fact that Namenda IR was never fully removed from the market due to a Court order,<sup>211</sup> this communications strategy was

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<sup>207</sup> FRX-AT-01780928-966 at 941. This presentation further stated that this “also suggests that the transition will start upon the announcement” of the Hard Switch strategy. See FRX-AT-01780928-966 at 941.

<sup>208</sup> FRX-AT-03872025-066 at 029. This presentation also noted: “In addition to a broad outreach communication plan to caregivers and AD professionals, the Forest sales force will provide information and resources to help make this a smooth transition.” See FRX-AT-03872025-066 at 027.

<sup>209</sup> OptumRx (also known as United Healthcare AARP) is the “largest Part D plan sponsor, representing over 25 percent of all volume for Namenda IR.” See Forest 30(b)(6) Deposition at 234:18-235:8; 260:14-262:17.

<sup>210</sup> FRX-AT-03684464-66 at 64. Thus, Optum was aware of the Hard Switch strategy before it was publicly announced. See, also, FRX-AT-03684533-35; FRX-AT-00950357-58.

<sup>211</sup> FRX-AT-01794662-4797; FRX-AT-01750160-0219.

successful for Forest in triggering wide-spread conversion to Namenda XR. In a December 2014 Declaration in the NYAG matter, William Meury of Actavis stated:

[B]ased on Forest's public announcements and course of dealing with its customers (including all major health plans and other managed care entities), there is an established expectation throughout the health care industry that Namenda XR will be distributed on a wide basis in the immediate future and that Namenda IR will be distributed through a specialty distribution channel (Foundation Care).<sup>212</sup>

104. Further, I have reviewed testimony which supports my conclusion that the Hard Switch strategy, though never fully implemented, affected physicians' decisions regarding patients. At a court hearing in the NYAG matter, Dr. James Lah was asked about a letter he received from Forest announcing the planned implementation of the Hard Switch strategy:

Q: Did you make any changes to your personal prescribing practices as a result of the letter from Forest?

A: Yes. We, because, because we expected that Namenda IR would be unavailable after August of this year, many of our patients are on multiple refills of their medication. So if it's a stable medication, I'll often authorize refills for up to a year. And we began to hear from pharmacies, and also as we were starting seeing patients in the clinic and renewing their medications knowing that Namenda IR would no longer be available past a certain date, we began switching patients from Namenda IR to Namenda XR.<sup>213</sup>

105. I discuss below Forest's communications with key stakeholders and customers following the Court's December 15, 2014 injunction preventing Forest from discontinuing Namenda IR.

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<sup>212</sup> FRX-AT-01747623-634 at 631. I discuss this specialty distribution channel for Namenda IR in greater detail below.

<sup>213</sup> FRX-AT-01750895-51082 at 50957; FRX-AT-01780565-66.

d. Evidence Demonstrating that the Court's Injunction to Prevent the Discontinuation of Namenda IR Did Not Eliminate the Anticompetitive Effects of the Hard Switch Strategy

106. I understand that on December 15, 2014, the U.S. District Court for the Southern District of New York “granted an injunction requiring Forest (and its parent company, Actavis (now Allergan)) to continue to make Namenda IR tablets available until thirty days after July 11, 2015,” and I understand that this injunction was affirmed by the Second Circuit on May 22, 2015.<sup>214</sup> Evidence I have reviewed demonstrates that this Court injunction did not eliminate the anticompetitive effects caused by Forest’s announcement and planned implementation of the Hard Switch strategy. I discuss this evidence in greater detail below.

107. As I previously discussed, given that AB-rated generic drugs typically capture a substantial portion of the market in a short period of time following their entry into the market, an important factor for a successful launch of Namenda XR was for Forest to transition as many patients as possible to Namenda XR prior to Forest’s loss of patent exclusivity on Namenda IR, at which time generic memantine hydrochloride products would be allowed to enter the market at dramatically lower prices than Namenda XR. Evidence I have reviewed demonstrates that, given the vulnerable nature of Alzheimer’s patients, it would be very difficult to convert them back to an IR memantine hydrochloride product such as Namenda IR once they had transitioned to Namenda XR.

108. For example, in a June 2012 email among Forest employees discussing a “Launch Readiness” presentation, Mark Devlin of Forest stated that “the key is not just conversion but also holding on to the XR business we get and not immediately losing it to generic IR. Managed care and LTC tells us that anyone converted [to Namenda XR] is likely to stay converted.”<sup>215</sup> A February 18, 2014 “Namenda Withdrawal Sales Force Training” presentation stated:

For patients who are still taking Namenda, we expect that most will transition to Namenda XR in advance of the discontinuation of Namenda. When generic

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<sup>214</sup> Complaint at ¶186; FRX-AT-01794662-4797; FRX-AT-01750160-0219.

<sup>215</sup> FRX-AT-01606209-210 at 209.

memantine becomes available, we anticipate that those patients who have already converted to Namenda XR will remain on therapy.<sup>216</sup>

A March 2014 Piper Jaffray analyst report covering Actavis stated that “switching a significant chunk of the market back to Namenda IR will be something of an uphill battle for generic entrants in our view (i.e., they will have to essentially promote their versions in order to make practices aware that there are IR dosage strengths available in pharmacies).”<sup>217</sup> A February 18, 2014 Morgan Stanley analyst report covering Forest stated: “Although many investors fear that payers will try to revert patients back to 2x/day starting in July 2015 when generics launch, we believe the market will largely stick with XR (1x/day) due to habit and the ability to sprinkle on food.”<sup>218</sup> At a January 21, 2014 Forest earnings call, Mr. Saunders of Forest stated:

[I]f we do the hard switch and we’ve converted patients and caregivers to once-a-day therapy versus twice a day, it’s very difficult for the generics then to reverse-commute back, at least with the existing Rx’s. They don’t have the sales force, they don’t have the capabilities to go do that. It doesn’t mean that it can’t happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again, go into a slow decline versus a complete cliff.<sup>219</sup>

109. Given the difficulty in transitioning patients back to an IR memantine hydrochloride product such as Namenda IR once they had already transitioned to Namenda XR, it is unlikely that the Court’s injunction preventing the discontinuation of Namenda IR would have succeeded in causing a substantial portion of these patients to transition back to Namenda IR, which would have allowed these patients to have a smooth transition to lower-priced generic memantine hydrochloride products when they became available. As shown in Figure 7 below, the introduction of generic memantine hydrochloride in July 2015 did not result in a sharp decline in DOT for Namenda XR, indicating that patients did not switch back to Namenda IR, and transition to generic memantine hydrochloride IR, in large quantities. Rather, the gradual decline in Namenda XR market share is consistent with the erosion of Namenda XR DOT as patients

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<sup>216</sup> FRX-AT-00953209-252 at 244.

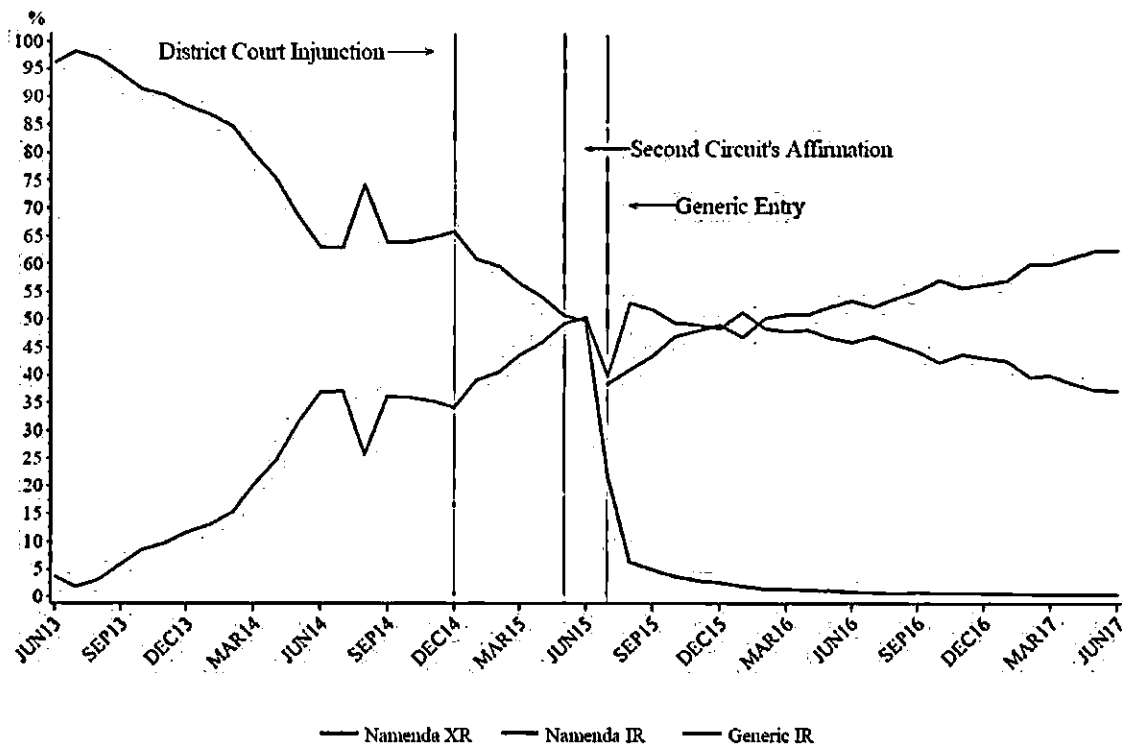
<sup>217</sup> FRX-AT-03587816-18 at 17.

<sup>218</sup> FRX-AT-01696384-6411 at 6386.

<sup>219</sup> FRX-AT-01775500-518 at 516.

transitioned off Namenda XR (either due to mortality or cessation of therapy) and were not replaced, as new patients started instead on generic memantine hydrochloride at much lower prices.

Figure 7  
Namenda XR, Namenda IR, and Generic IR Market Shares



Source: NPD Data.

110. Further, earlier in this Expert Report I discussed how a key part of Forest's strategy for maximizing conversions to Namenda XR following the announcement of the Hard Switch strategy was to embark on a broad communications initiative with key stakeholders and customers in order to inform them Namenda IR would no longer be available as of a certain date with enough lead time to afford patients a smooth transition to the new product with minimal disruption of treatment. I discuss below Forest's communications with key stakeholders and customers following the Court's December 15, 2014 injunction preventing Forest from discontinuing Namenda IR.

111. In a January 2015 email following the Court's injunction, Namenda XR sales representatives and managers were informed of the communications that were sent to

their customers regarding “NAMENDA tablet availability.”<sup>220</sup> In this email, Forest instructed its Namenda XR salesforce that:

If you get questions about these letters or the plans for IR, please communicate:

Actavis plans to continue the sale of NAMENDA tablets according to the court order.

We have appealed this decision and expect more information to be available in February.

NAMENDA XR offers benefits to patients and caregivers including once daily dosing and the ability to sprinkle on applesauce. And then continue into your Namenda XR message.<sup>221</sup>

112. In a January 9, 2015 email among Forest employees regarding the Court-ordered communication Forest was required to send to physicians, pharmacists, caregivers, and managed care plans regarding the continued availability of Namenda IR, Forest gave the following instruction:

Some of the communications will include language that says we are appealing the court decision [...]. If you get questions regarding this, I think we should say that yes we are appealing the decision and expect to have resolution in middle of February. [...] If you get general questions about the availability of Namenda IR tablets, please continue to say that Namenda tablets currently remain available.<sup>222</sup>

113. In a January 6, 2015 press release that was added to Actavis’ investor relations website, the company noted that the Appeals Court had agreed to hear its case regarding the Court’s injunction and that it was “optimistic that the Court will overturn the lower court’s unprecedented ruling.”<sup>223</sup> This press release further stated:

Actavis reiterated that the District Court ruling will have no impact on its ability to continue focusing its resources on transitioning patients to the convenient and

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<sup>220</sup> FRX-AT-03745356-58.

<sup>221</sup> FRX-AT-03745356-58 at 57. This email further instructed the Namenda XR salesforce: “As you know, our goals with NAMENDA XR remain unchanged and we continue to make progress on them: \* To reinforce the benefits offered by NAMENDA XR [...] \* To transition upwards of 70% to 80% of patients to Namenda XR based on the benefits of NAMENDA XR, and [...] To increase the overall demand for NAMENDA XR.” See FRX-AT-03745356-58 at 58.

<sup>222</sup> FRX-AT-04283678-79.

<sup>223</sup> FRX-AT-03982972-75 at 72.



innovative once-daily NAMENDA XR®, and that the Company is prepared to manage its business in a way that provides the least disruption in its ability to support the marketplace and minimize any financial impact.<sup>224</sup>

114. In a pop-up message on the Namenda website following the Court’s injunction, Forest stated that it planned to continue selling Namenda IR per the Court’s order, but also noted that it planned to appeal the order.<sup>225</sup> Further, evidence I have reviewed indicates that on January 5, 2015, a few weeks after the Court’s injunction, Forest embarked on an extensive “Direct-to-Consumer” campaign for Namenda XR in order to “raise awareness” of the drug.<sup>226</sup> In a May 22, 2015 Actavis press release following the Appeals Court decision to uphold the Court’s injunction, Mr. Saunders stated: “While we are disappointed by the Court’s decision to uphold this ruling, we intend to continue our strong efforts to convey the significant benefits of NAMENDA XR® to physicians, patients and caregivers.”<sup>227</sup>

115. Evidence I have reviewed indicates that, just prior to the Court’s injunction, Forest planned to make Namenda IR available, but on a limited basis. For example, on November 5, 2014, six weeks after the New York Attorney General filed its motion for a preliminary injunction, that:

Forest announced that based on feedback from doctors it would not totally discontinue Namenda IR, and had partnered with a specialty pharmacy, Foundation Care,<sup>228</sup> to make Namenda IR available through mail order for any patient whom a doctor believed had a medical necessity for Namenda IR.<sup>229</sup>

116. Evidence I have reviewed indicates that physicians were often hesitant to prescribe Namenda IR following the Court’s injunction since they were unsure as to what constituted a “medical necessity” in determining which medication to prescribe. For example, Dr. James Lah, Associate Professor of Neurology at Emory University and

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<sup>224</sup> FRX-AT-03982972-75 at 72.

<sup>225</sup> FRX-AT-01819478-81 at 78.

<sup>226</sup> See, for example, FRX-AT-01829171-73; FRX-AT-04363541-48; FRX-AT-04051660-62 at 61.

<sup>227</sup> FRX-AT-03671360-64 at 60.

<sup>228</sup> Foundation Care is a “full service specialty mail order pharmacy serving patients nationwide.” See FRX-AT-01783493-514 at 495.

<sup>229</sup> FRX-AT-03982321-24 at 24. In a December 12, 2014 Declaration from Daniel Blakeley of Foundation Care, Mr. Blakeley stated that the “Namenda IR Foundation Care program will be fully operational by January 1, 2015, pursuant to the terms of the agreements.” See FRX-AT-01749967-970 at 970.

Clinical Core Leader of the Emory Alzheimer's Disease Research Center, testified to the following at a Court hearing in the NYAG matter:

Q: Would you be uncomfortable signing this [medical necessity] form for most of your patients even though they might, even though you might prefer that they continue on IR instead of switching to XR?

A: Yes. [...]

Q: Does Forest's limited distribution plan, like discontinuation of the Namenda IR, interfere with your ability to choose Namenda IR tablets for any patients?

A: Yes, I believe it does.

Q: And why do you say that?

A: Because in order to continue a patient on Namenda IR and not switch them to Namenda XR, I would have to declare that it was medically necessary for an individual to remain on Namenda IR. I don't know if that comes with any legal ramifications or penalty on, to do, to do so, without good justification. But in my mind there is not a good justification based on what I know or don't know about Namenda IR versus XR that would reach that threshold of concern that would cause me to declare that a particular version of the drug was medically necessary for an individual.<sup>230</sup>

117. Further, at a November 13, 2014 hearing in the NYAG matter, Dr. Barry Reisberg, a physician retained by the Defendants in that matter, testified that, at that time, he did not see "any medical need for the IR tablets," citing the availability of Namenda XR.<sup>231</sup> This evidence further demonstrates the unlikelihood that the Court's injunction

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<sup>230</sup> FRX-AT-01750895-51082 at 50962-50966. Dr. Lah continued: "So I'm not sure I would be comfortable continuing to prescribe Namenda IR if it were required me to declare that it was medically necessary for an individual to stay on that drug, when another perfectly good drug, Namenda XR, which may also be perfectly safe and effective may also be available for that patient." See FRX-AT-01750895-51082 at 50965-50966. Dr. Lah also testified: "Q. Are you aware of any other pharmaceutical manufacturer that has imposed a requirement of an indication that a drug is medically necessary before that drug is prescribed for a patient? A. Not that I can recall. When we are required to submit paperwork for medications, it tends to come from insurance companies that restrict access or coverage to certain medications without documentation for an appropriate use of that drug. But I'm not – I can't think of another instance where such a document is imposed by a drug company." FRX-AT-01750895-51082 at 50965.

<sup>231</sup> FRX-AT-01751482-1646 at 1627-1629.

would have succeeded in eliminating the entirety of the anticompetitive effects of Forest's Hard Switch strategy.

118. Additional evidence I have reviewed demonstrating that the Court's injunction was unlikely to have eliminated the anticompetitive effects of Forest's Hard Switch strategy includes evidence that pharmacies and health insurance plans no longer covered Namenda IR following the Court's injunction, or changed its status to non-preferred. For example, a February 18, 2015 email among Actavis employees regarding Namenda XR conversion noted the "sixth week in a row [with] zero utilization for Namenda IR" for Omnicare, a pharmacy specializing in long term care facilities, which was acquired by CVS Health in 2015.<sup>232</sup> It was later confirmed by Amy Turturice that "Omnicare no longer has Namenda IR on contract as of 1/31/15."<sup>233</sup> Further, in a January 27, 2015 email among Actavis employees discussing a "January 26 XR salesforce update," Erin Newton of Actavis discussed "recent changes in formulary status of Namenda IR," noting that this status was changed to "Non-Preferred on OptumRx/AARP and to NOT COVERED on Aetna Part D, Cigna/Health-Spring Part D and Coventry Part D."<sup>234</sup>

e. A Structural Break Test Confirms Forest's Hard Switch Scheme

119. In order to evaluate whether Forest's announcement of the Hard Switch had an impact on the market, I conducted a statistical analysis of conversion to Namenda XR using market share data from NSP. Statistical testing in the form of a structural break test reveals that the Hard Switch from Namenda IR to Namenda XR was effective in converting more Namenda IR prescriptions to Namenda XR than otherwise would have been the case. Specifically, I performed a structural break test by regressing the actual Namenda XR conversion rate on a time trend variable, a time trend variable interacted with a February 2014 hard switch variable, and a dummy variable for August 2014.<sup>235</sup> If

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<sup>232</sup> FRX-AT-03910305-311 at 306; CVS Health Corporation, "CVS Health and Omnicare Sign Definitive Agreement for CVS Health to Acquire Omnicare," May 21, 2015. Available at <https://cvshhealth.com/newsroom/press-releases/cvs-health-and-omnicare-sign-definitive-agreement-cvs-health-acquire-omnicare>.

<sup>233</sup> FRX-AT-03910305-311 at 305.

<sup>234</sup> FRX-AT-03573080-82 at 80. Ms. Newton further stated, "we must do our part in the office and the pharmacy to ensure that ALL of these patients are switched to Namenda XR." See FRX-AT-03573080-82 at 80.

<sup>235</sup> I have used the Namenda XR conversion rate calculated using the NSP data from June 2013 to June 2015 for this regression analysis. The time trend variable equals 1, 2, 3, ..., 25 for June 2013, July 2013,

the estimated coefficient for the interaction term of the trend variable and the February 2014 hard switch variable is positive and statistically significant, it indicates that the hard switch starting from February 2014 increased the Namenda XR conversion rate compared to the Namenda XR conversion rate under the soft switch. The regression result shows that the estimated coefficient is positive (at 0.83 percent) and statistically significant (with a *p*-value of 0.033), which means that there is a structural break in the Namenda XR conversion rate at the time the Hard Switch strategy was implemented beginning February 2014.

120. In sum, for the reasons discussed above, I have concluded that proposed Class members were impacted by the allegedly anticompetitive agreement Defendants entered into with Mylan, assuming, as Plaintiffs allege, that it resulted in delayed entry of generic memantine hydrochloride into the market,<sup>236</sup> and/or by Forest's Hard Switch scheme in that all or nearly all Class members paid higher prices for brand-name Namenda than they otherwise would have for generic memantine hydrochloride, and/or they paid more for generic memantine hydrochloride than they otherwise would have.

## VI. Measurement of Class-Wide Damages

121. I have been asked by Counsel for Plaintiffs to measure class-wide damages resulting from Defendants' allegedly anticompetitive agreement and/or Forest's announcement and implementation of the Hard Switch. Based on my training and experience in economics and my analysis of the data produced to me in this matter (discussed above), I have applied benchmark methodologies to measure damages

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August 2013, ..., June 2015. The February 2014 switch variable equals 0 prior to February 2014 and equals 1 from February 2014 onward. Forest formally and publicly announced its intention to discontinue sales of Namenda IR on February 14, 2014. See FRX-AT-00956973-75 (February 14, 2014 Press Release on discontinuance). I have included the dummy variable for August 2014, which equals 1 for August 2014 and 0 otherwise, to control for the XR supply shortage in August 2014. See FRX-AT-03910390-94 at 393.

<sup>236</sup> Again, I understand that Plaintiffs intend to prove that but for the allegedly unlawful Forest/Mylan agreement, Mylan would have launched generic Namenda IR earlier, either in June 2012 had there been no alternative settlement, or in November 2012 (under an alternative settlement) and that other generic manufacturers (at least Amneal, Dr. Reddy's, and Sun) would have entered at those same times under their own agreements with Forest. I also understand that Plaintiffs may allege that Lupin and an authorized generic would also have launched at those same times. Additional generics also may have launched earlier than they actually did, but such additional generics would not change the model, since generic prices by 2015, with four generics launching in 2012, would already have decreased basically as much as they would have even if more generics had been in the market earlier as well.

associated with each of the two components of the alleged misconduct. I discuss this methodology in more detail below.

*A. Defendant's and Generic Manufacturers' Transaction-Level Data*

122. In order to measure class-wide damages, I compared the prices for Namenda and generic memantine hydrochloride paid by proposed Class members in the actual world with those they would have paid in a world free of the alleged misconduct. I also compared the volume of transactions for lower-priced generic memantine hydrochloride in the actual and but-for worlds. I have analyzed both the NSP data<sup>237</sup> discussed above and the transaction-level data produced by Forest and some of the generic manufacturers (Amneal, Dr. Reddy's, Lupin, Mylan, Teva, and Wockhardt) for the purposes of measuring aggregate and individual damages.

123. Defendant Forest produced transaction-level data for the period from January 2010 through July 2017. Some third-party generic manufacturers produced transaction-level data for the following time periods: Amneal from July 2015 through May 2017, Dr. Reddy's from July 2015 through February 2017, Lupin from July 2015 through September 2016, Mylan from July 2015 through July 2016, Teva from July 2015 through March 2017, and Wockhardt from November 2015 through December 2016.<sup>238</sup> Sun and Macleods, two other third-party generic manufacturers, produced aggregated sales data. Sun produced quarterly sales data by customer and product from July 2015 through June 2017. Macleods produced monthly sales data by product from October 2015 through

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<sup>237</sup> Because I do not have transaction-level data from all generic manufacturers, I rely on the NSP data to calculate market-wide statistics, such as generic penetration rate, XR conversion rate, total market DOT, and market shares of Namenda IR and XR and generic memantine hydrochloride.

<sup>238</sup> AMNEAL0009290; DRL (Namenda AT Litig)0001798; DRL (Namenda AT Litig)0003686; LPI-NMDA-00000005 - LPI-NMDA-00000006; Memantine report; MYLMEMA\_000001 - MYLMEMA\_000002; NAMENDA.SUN0010776; SUN0010777 - 2017-08-23 Memantine Sales Info BY QUARTER; TEVANIR-00003877 - TEVANIR-00003878.

August 2017. I determined that the aggregated data produced by Sun<sup>239</sup> and Macleods<sup>240</sup> were unreliable, so I did not analyze them further. Transaction-level data from Unichem, Aurobindo, Alembic, Upsher-Smith, Ajanta, and Torrent were not available to me at the time I prepared this Expert Report. Therefore, my analyses were limited to the transaction-level data produced by Forest, Amneal, Dr. Reddy's, Lupin, Mylan, Teva, and Wockhardt. I reserve the right to revise my analyses accordingly should I receive additional usable sales data in the future.

124. The transaction-level data produced by Forest and some of the generic manufacturers included information on the customer, product, quantity, and sales amount. In order to use these data in my analysis, it was necessary to make several adjustments, including:

- a. The identification and exclusion of sales to a Defendant's own entities and sales to other Defendants;
- b. Removal of sample or free-of-charge transactions;
- c. Removal of sales to government entities;
- d. Removal of non-class products;
- e. Matching of rebates, price adjustments, and chargebacks to individual transactions in order to calculate a net sales amount;<sup>241</sup>

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<sup>239</sup> Sun's quarterly aggregated sales data appear to be flawed and cannot be used to calculate reasonable prices across customers. See "NAMENDA.SUN0010776.xlsx," received on August 2, 2017. The data flaw can be found in "Qtr 4-17 to 6-17", "Qtr 1-17 to 3-17", "Qtr 10-16 to 12-16", "Qtr 7-16 to 9-16", and "Qtr 4-16 to 6-16" tabs. For example, in "Qtr 4-17 to 6-17" tab, for item code 1115165 and customer Amerisource, the quantity is 60 and the sales \$ is 9.11. The unit price would be \$9.11/60, which is \$0.15 per unit. For the same item code and customer McKesson, the quantity is 923 and the sales \$ is 23100.12. The unit price would be 23100.12/922, which is \$25.05 per unit. It makes no sense that the calculated unit price is \$0.15 for Amerisource but over \$25 for McKesson. SUN sent an updated file "SUN0010777 - 2017-08-23 Memantine Sales Info BY QUARTER.xlsx" on August 23, 2017, which does not resolve the issue. The Sun data, though, can be used to identify direct purchasers.

<sup>240</sup> Macleods' monthly aggregated sales data were excluded as the NSP data suggests that the total sales should be three times larger. See "HIGHLY CONFIDENTIAL Macleods Memantine.pdf," received on September 5, 2017. The total sales in this pdf file is \$2,577,721.19 from October 2015 to August 2017. According to the IMS data, the total sales is \$10,066,192 from October 2015 to June 2017.

<sup>241</sup> Dr. Reddy's and Wockhardt produced a net sales amount that already included the adjustment of rebates, chargebacks, and other price adjustments. For Forest, Amneal, Lupin, Mylan, and Teva, the rebates, chargebacks, and other price adjustments were contained in separate transactions. Therefore, I applied these adjustments to the individual sales transactions in order to calculate a sales amount net of rebates, chargebacks, and other price adjustments for each sales transaction.

- f. Calculation of DOT (using the same method as described above for the NSP data);<sup>242</sup> and
- g. Calculation of net price per day (net sales amount divided by the DOT for each product).

*B. Types of Direct Purchaser Damages*

125. As I discuss in greater detail below, damages suffered by proposed Class members in this matter as a result of Defendants' alleged misconduct can be categorized as one of two types. The first type relates to higher prices paid by proposed Class members for the branded Namenda they purchased rather than the lower-priced generic memantine hydrochloride they would have purchased in the but-for world absent the alleged misconduct, which precluded a substantial share of the market from switching to generic memantine hydrochloride. That is, had generic memantine hydrochloride been available in the market in June 2012 or, alternatively, on November 2, 2012, my analysis indicates that a large volume of branded Namenda IR and Namenda XR purchases in the actual world would have been replaced by generic memantine hydrochloride in the but-for world, and the price paid for generic memantine hydrochloride would have been dramatically lower. Further, had Forest not engaged in the Hard Switch strategy, fewer patients would have switched to Namenda XR, and proposed Class members would have purchased a larger share of lower-priced generic memantine hydrochloride than they actually did. I refer to the damages arising from the foreclosure of this switching to generic memantine hydrochloride resulting from Defendants' alleged misconduct as "Brand-Generic" or "B-G" damages. For the purpose of calculating Brand-Generic damages, I calculated the price differential between actual average monthly Namenda IR and Namenda XR prices and but-for average monthly generic memantine hydrochloride prices from June 2012 (or in the alternative, November 2, 2012) to June 2017, the last date for which NSP data are available. I also calculated the price differential between the actual average Namenda XR monthly prices and but-for average monthly generic

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<sup>242</sup> Since Namenda XR is taken once a day, the DOT is the same as the produced quantity times the package size (that is, the number of pills in the package). For Namenda IR and generic memantine hydrochloride, the DOT is calculated as the produced quantity times the package size times 0.5 because Namenda IR and generic memantine hydrochloride are taken twice a day.



memantine hydrochloride prices from June 2012 (or in the alternative, November 2, 2012) to June 2017. Damages are measured as the price difference multiplied by the volume of Namenda IR and Namenda XR which would have been switched to generic memantine hydrochloride in the but-for world. I discuss the calculation of the volume of generic memantine hydrochloride in the but-for world below.

126. The second type of damages relates to the higher prices proposed Class members paid for the generic memantine hydrochloride they actually purchased due to delayed generic entry. In other words, in addition to damages reflecting the earlier substitution of generic memantine hydrochloride for Namenda IR and Namenda XR in the but-for world, direct purchasers suffered additional damages because the prices they paid for the generic memantine hydrochloride they actually purchased were higher than they would have been had generic memantine hydrochloride entered the market earlier. This is because, as I noted above, prices for generic drugs tend to decline over time as generic manufacturers compete against each other. I refer to the damages arising from lower prices for generics in the but-for world as “Generic-Generic” or “G-G” damages. For the purpose of calculating the Generic-Generic damages, I determined the price differential between the actual generic price and the but-for price of generic memantine hydrochloride from July 2015 to June 2017.<sup>243</sup>

### *C. No Reverse-Payment But-For World*

127. I have been asked by Counsel for Plaintiffs to determine whether the amount of class-wide damages suffered by proposed Class members under the No Reverse-Payment But-For World can be calculated in the aggregate using a class-wide, formulaic method without resorting to individual inquiry. Based on my training and experience in economics and my analysis of the data produced to me in this matter (discussed above), I have determined that a benchmark analysis based on the “before and after” methodology may be used to measure class-wide damages in the aggregate. I discuss this methodology in more detail below.

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<sup>243</sup> To determine the but-for generic price, I calculated the ratio of the average generic price to the average branded Namenda IR price by month and then multiplied that by the average branded Namenda IR price to get the but-for generic price.



i. Analysis of But-For Generic Entry Date Performed by Professor Einer Elhauge

128. I understand that Plaintiffs retained Professor Einer Elhauge of Harvard University to analyze the question of what alternative generic entry date Forest and Mylan would have agreed to in a settlement agreement without a large reverse payment. I have relied on an instruction from Counsel for the Plaintiffs regarding the date on which generic memantine hydrochloride would have entered the market, and the generic manufacturers who would have entered.

129. Based on instruction from Counsel for the Plaintiffs, I have modeled November 2, 2012 as the date for generic entry in a world without the Forest/Mylan reverse payment agreement. Further, I have assumed, based on instruction from Counsel for the Plaintiffs, that entry by Mylan would have meant earlier entry by at least Dr. Reddy's, Sun, and Amneal as well. I have been instructed by Counsel that, had Forest and Mylan not reached an alternative, pro-competitive settlement with a November 2012 entry date (but no large reverse payment), Plaintiffs' expert, George Johnston, has opined that Mylan would have prevailed in the patent litigation brought against it by Forest and would have obtained a final, non-appealable judgment by June 2012, and entered at that time. Here again, I understand that entry by Mylan in June 2012 would have resulted in entry by (at least) Amneal, Sun, and Dr. Reddy's as well. In analyzing generic entry, I understand from Counsel for the Plaintiffs that Professor Elhauge has opined that Forest would have launched Namenda XR 12 months prior to the date it believed generics would enter the market. Accordingly, I have assumed that Namenda XR would have entered the market in either June 2011 or November 2, 2011.

ii. Methodology

130. I was asked by Counsel for Plaintiffs to determine the amount of class-wide damages, if any, arising from the delayed entry of AB-rated generics into the memantine hydrochloride market and/or from the Hard Switch. That is, I was asked to measure damages suffered by the proposed Class in the form of higher prices for Namenda IR and XR paid during the period when generic competition was allegedly impaired by Forest's agreement with Mylan together with the Hard Switch, and asked whether such damages

can be measured in the aggregate. Further, to analyze damages arising from the Hard Switch alone, I assume that Forest would have pursued a conventional switch or Soft Switch instead. There are two sources of damages based on Plaintiffs' allegation regarding Forest's pay-to-delay agreement: (1) damages resulting from proposed Class members' purchases of higher-priced branded Namenda IR and XR (instead of lower-priced generic memantine hydrochloride) as a result of the delay in generic entry and Defendants' Hard Switch strategy for Namenda XR; and (2) damages resulting from proposed Class members paying prices for generic memantine hydrochloride products after actual generic entry in July 2015 that were higher than they would have been had generic entry occurred earlier.

131. A benchmark analysis can be used to measure the overcharge resulting from the alleged anticompetitive conduct in this matter. In a benchmark analysis, the overcharge is calculated by comparing the price that arose as a result of the alleged conduct with the price for that product in some other market or during some other period of time in which pricing was not affected by the alleged anticompetitive conduct. One commonly adopted benchmark compares prices for the same good in the same market at different points in time (e.g., during a period affected by anticompetitive conduct and during some period not affected by the alleged scheme). The benchmark methodology is an accepted method for calculating damages in the field of antitrust economics.<sup>244</sup> It is my opinion that the period after the actual entry of generic memantine hydrochloride provides a reliable benchmark period. This type of benchmark analysis has been widely used for many years in calculating damages that arise from anticompetitive conduct of the sort alleged in this case.<sup>245</sup> The prices that occurred after the actual entry of generic memantine hydrochloride in July 2015 provide information that may be used to construct a competitive benchmark. Therefore, I use the period after generic memantine hydrochloride entered the market as a benchmark for the conditions in the market that would have prevailed had generic entry occurred earlier, in June 2012 or November 2012. The aggregate damages can be calculated based on prices and volume (DOT)

<sup>244</sup> Herbert Hovenkamp, *Federal Antitrust Policy*, St. Paul, MN: West Publishing Co., 1994 at §17.5b.

<sup>245</sup> See, for example Robert B. Bergstrom, "The Role of the Expert in Proving and Disproving Damages in Antitrust Claims," *Antitrust Bulletin*, Vol. 11 (1966) at pp. 677-706.

using the NSP data. However, as an alternative, I have used the transaction-level sales data produced by Forest and various generic manufacturers (as discussed above) to quantify the aggregate damages to proposed Class members as well as allocating damages to individual proposed Class members (see Exhibit 1).

### iii. Calculation of But-For Prices

132. For the purposes of my analysis, I have used a but-for generic entry date of June 2012 (37 months before actual entry in July 11, 2015) or in the alternative, November 2, 2012 (32 months before the actual generic entry date of July 11, 2015) based on Professor Elhauge's analysis. The specific but-for generic entry date does not affect the nature of my proposed damages methodology, although it will affect the quantum of damages. If, at a later stage in this matter, a determination is made that the but-for entry date would have occurred at some other time, the same methodology would apply. Moreover, I reserve the right to revise this analysis as more information becomes available.

133. In order to determine the prices for Namenda IR, Namenda XR, and generic memantine hydrochloride, I relied on the NSP data. To calculate the but-for generic prices, I first calculated the average monthly prices of generic memantine hydrochloride products and the average monthly prices of Namenda IR products that occurred in the actual world from July 2015 to June 2017, when the NSP data available to me at the time I prepared this Expert Report end. I then calculated the ratio of the average generic IR price and the average Namenda IR price and multiplied that by the average branded Namenda IR price to get the but-for generic IR price. I have assumed that generic memantine hydrochloride prices would have remained constant at the same level after the end of my historical data on prices. The use of generic prices that occurred in the actual world following generic entry in July 2015 is an appropriate and conservative benchmark to measure generic but-for prices that would have prevailed had generic entry occurred on June 2012 (or November 2, 2012). This is because generic entry would have worked in a similar fashion to reduce prices for generic memantine hydrochloride had generic entry occurred earlier in time. Further, assuming that generic prices are constant after June 2017 is conservative because price-based competition among generic manufacturers would have pushed prices for generics downward after June 2017. I then shifted back the

actual generic memantine hydrochloride prices 37 months (i.e., from July 2015 to June 2012) (or, alternatively, 32 months from July 2015 to November 2012) to obtain but-for generic memantine hydrochloride prices.

134. For those months where I did not have data on Namenda XR prices, I calculated the Namenda XR price using the same ratio approach as used for the average generic memantine hydrochloride price. That is, I calculated the ratio of the average Namenda XR price and the average Namenda IR price and multiplied that by the average Namenda IR price. The Namenda IR average price can be calculated directly using the NSP data or Forest's transaction-level sales data. For the purpose of calculating actual Namenda IR and Namenda XR prices and comparing them with the but-for prices for generic memantine hydrochloride, I relied on the NSP data and the transaction-level data produced by Forest, as well as some of the generic manufacturers.

iv. Behavior of Namenda XR in the but-for world

135. For the purposes of my analysis, I have assumed that Namenda XR would have been launched 12 months before generic memantine hydrochloride was introduced to the market, either in June 2011 or, in the alternative, on November 2, 2011, based on Professor Elhauge's analysis. I have also assumed that once Namenda XR was introduced to the market, its market share would have steadily increased, ultimately achieving a 30 percent market share 12 months after it entered the market, at which point lower-priced generic memantine hydrochloride would enter.<sup>246</sup> I have assumed that at the point when generics enter the market, Namenda XR's market share would begin to decline until it was no longer sold in the market. This behavior is based on the performance of Namenda XR in the actual world from 2013 to 2017, as well as my analysis of Namenda sales, and represents a conservative approach to measuring class-

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<sup>246</sup> This is very conservative, as 30 percent conversion likely would have taken 18 months (as I discuss below), and with generic entry looming in only 12 months, the evidence I have reviewed suggests that managed care would not have supported a switch.

wide damages. I have assumed that Forest did not implement the Hard Switch strategy for Namenda XR.

v. Calculation of But-For Volumes

136. In order to calculate the Brand-Generic damages, I estimated the total volume of proposed Class members' purchases of Namenda IR and XR that would have switched from brand Namenda to generic memantine hydrochloride during each month from June 2012 (or in the alternative November 2012) to June 2017. To do so, I first determined the market share of Namenda XR in the but-for world, and then calculated the total market share of branded Namenda IR in the but-for world. The market share of generic memantine hydrochloride in the but-for world can then be calculated by multiplying the total market share of memantine hydrochloride IR in the but-for world by the generic penetration rate, where the generic penetration rate is the share of memantine hydrochloride IR that would have been captured by generic memantine hydrochloride.<sup>247</sup>

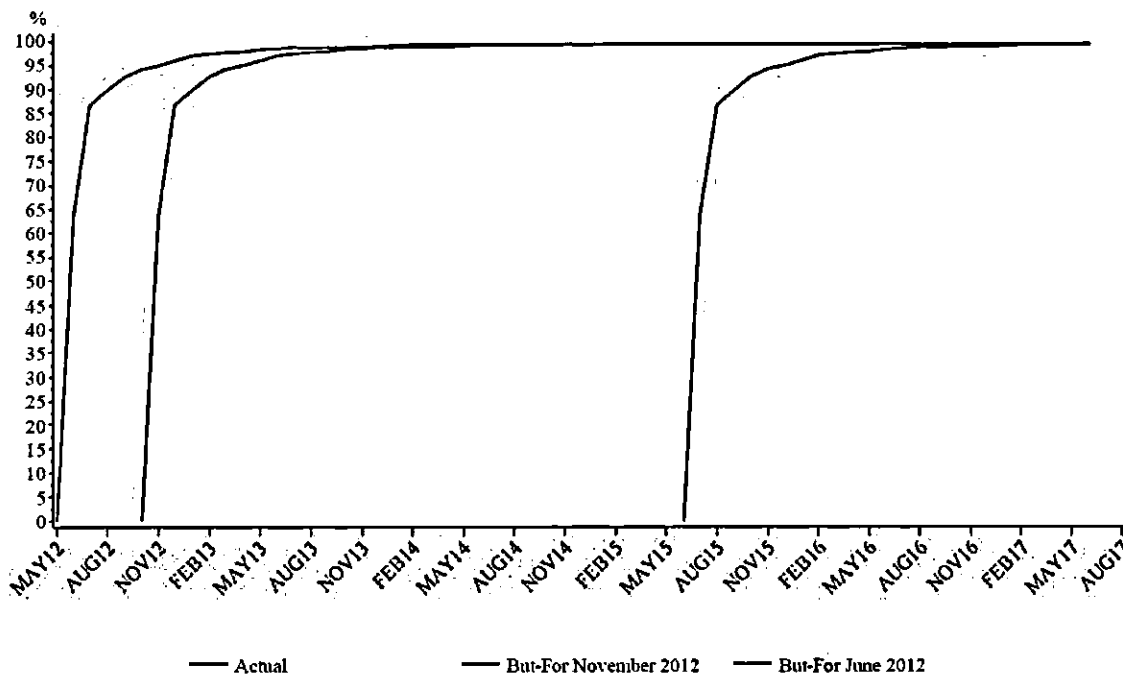
137. The generic penetration rate is calculated using the total DOT of generic memantine hydrochloride divided by the total DOT of generic memantine hydrochloride plus Namenda IR in each month after the actual generic entry date. I calculated the generic penetration rate using the NSP data because I did not have complete data on generic manufacturers' sales of memantine hydrochloride at the time I prepared this report (no data was provided for a number of generic manufacturers, and some of the data supplied was inadequate to determine generic penetration). I then applied the resulting generic penetration rate profile to the period beginning at the but-for generic entry date (June 2012, and in the alternative, November 2012).

138. Figure 8 below demonstrates the generic penetration rate and the but-for generic penetration rates.

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<sup>247</sup> Brand-Generic damages reflect the higher prices paid by proposed Class members who would have switched to lower-priced generic memantine hydrochloride had the generics entered the market earlier. I multiplied the actual total DOT of Namenda IR and XR by the generic penetration rate in the but-for world to account for the fact that some patients may want to stay on Namenda IR and XR after the but-for generic entry date.

Figure 8  
Generic Penetration Rate



Source: NSP Data.

vi. Measurement of Damages Under the No Reverse-Payment But-For World

139. As I discussed above, the Brand-Generic damages can be calculated as the difference between the actual price of Namenda IR and XR and the but-for generic memantine hydrochloride price, multiplied by the volume (measured in DOT) of generic substitution by proposed Class members that was hindered by the delay in generic entry in the but-for world. These damages continue as long as the volume of generic sales in the but-for world exceeds that in the actual world, since the brand price is always higher than the generic price. This formula can be used to calculate damages using the NSP data for each month from June 2012 (or in the alternative November 2, 2012) through June 2017.

140. After the date at which generic entry actually occurred, those purchases of generic memantine hydrochloride by proposed Class members occurred at higher prices than would have prevailed had generic entry occurred on June 2012 (or November 2, 2012). This is so because, as discussed above, competition among multiple generic competitors

bids the generic price down toward marginal cost. But this process is not instantaneous; it takes some time, as can be seen in the data regarding actual generic prices from July 2015 through June 2017. If generic entry had occurred years earlier, as Plaintiffs allege, this price competition would have begun earlier as well, so that by the time proposed Class members made actual purchases of generic Namenda IR after July 2015, but-for generic prices would have been lower (due to the price competition having started in 2012 instead of 2015). These Generic-Generic damages can be calculated as the difference between the actual and the but-for generic memantine hydrochloride price multiplied by the generic volume purchased in the actual world. This formula can be used to calculate damages using the NSP data or the transaction-level data for each month from July 2015 through June 2017.

141. The application of the above damages methodology yields the aggregate overcharges suffered by proposed Class members. The aggregate damages calculated using the NSP data are shown below in Table 2. As shown, total damages estimated using the NSP data are \$6.09 billion assuming a but-for-generic entry date of November 2, 2012, and \$6.82 billion assuming a but-for generic entry date of June 2012. Table 2 also shows aggregate damages calculated using the transaction-level data produced by Forest and some generic manufacturers. The only modification is that I calculated the average monthly prices of Namenda IR, Namenda XR, and generic memantine hydrochloride using the transaction-level data instead of the NSP data. The DOTs for Namenda IR, Namenda XR, and generic memantine hydrochloride and the generic penetration rate are still calculated using the NSP data because generic manufacturers' transaction-level data was incomplete at the time I prepared this report. As shown, total damages estimated using the transaction-level data are \$6.18 billion assuming a but-for-generic entry date of November 2, 2012, and \$6.93 billion assuming a but-for generic entry date of June 2012. Using the transaction-level sales data yields similar and slightly higher damages than using the NSP data, therefore, the aggregate damages I calculated using the NSP data in Table 2 below are reliable and conservative.



**Table 2**  
**Aggregate Reverse-Payment Damages by But-For Generic Entry Date**

<b>Damages Type</b>	<b>November 2, 2012</b>		<b>June 2012</b>	
	<b>NSP Data</b>	<b>Transaction-Level Data</b>	<b>NSP Data</b>	<b>Transaction-Level Data</b>
Brand-Generic	\$6,058,542,837	\$6,097,532,223	\$6,790,865,089	\$6,852,249,306
Generic-Generic	\$32,939,026	\$78,353,141	\$32,939,026	\$78,353,141
<b>Total</b>	<b>\$6,091,481,863</b>	<b>\$6,175,885,364</b>	<b>\$6,823,804,115</b>	<b>\$6,930,602,447</b>

Source: NSP data & transaction-level sales data.

142. The transaction-level sales data allow me to calculate customer-specific sales volume and prices for some purchases and provides additional evidence showing that all, or nearly all, proposed Class members were harmed. For every direct purchaser in the transaction-level data, the individual Brand-Generic damages are positive, additional evidence showing that all or nearly all proposed Class members were harmed by Forest's alleged anticompetitive pay-to-delay scheme. Among the 29 generic-only customers for whom I have sufficient generic sales data to calculate the Generic-Generic damages, all 29 customers had positive damages, which means that all, or nearly all, generic-only customers were harmed by Forest's alleged anticompetitive pay-to-delay scheme. For this analysis, I used the individual customer's price and sales volume from the limited transaction-level data I currently have, and, therefore, reserve the right to update this analysis when more usable transaction-level data become available to me at a later stage in this litigation.

*D. No Hard Switch But-For World*

143. I was also asked by Counsel for Plaintiffs to measure class-wide damages under the No Hard Switch But-For World. That is, I was asked to measure class-wide, aggregate damages resulting from Defendants' anticompetitive Hard Switch scheme, a strategy often referred to as a "product hop." For purposes of this analysis, I do not change the date of entry of generic Namenda IR, but leave it as it actually occurred in July 2015. As I discussed above, in this but-for world, Namenda XR would continue to be introduced to the market in June 2013, but the Defendant Forest would not have engaged in the Hard Switch conduct discussed above, including the public and private



announcements that Namenda IR would be discontinued (along with the other related communications made to managed care, doctors, caregivers, and patients). Moreover, in this scenario, I assume that generic memantine hydrochloride (immediate release) would still have come to the market in July 2015. Based on my training and experience in economics and my analysis of the data produced to me in this matter (discussed above), I have determined that a method exists which may be used to formulaically measure class-wide, aggregate damages resulting from Forest's Hard Switch strategy. I discuss this method in greater detail below.

i. Professor Berndt Opines that Forest Internal Forecasts for Namenda XR Conversion Rates are Reliable

144. I understand that Plaintiffs have retained Professor Ernst Berndt, the Louis E. Seley Professor in Applied Sciences in Applied Economics at the Sloan School of Management at the Massachusetts Institute of Technology, to discuss the use of internal company forecasts as a means of calculating damages from the Hard Switch in this matter. In particular, I understand that Professor Berndt has reviewed Forest's own forecasts of the likely conversion rate from Namenda IR to Namenda XR prepared as part of Forest's own analysis. I further understand that it is Professor Berndt's opinion that these forecasts of the Namenda XR conversion rate are a reliable basis for an analysis of the incremental effect of the Hard Switch on the conversion from branded Namenda IR to branded Namenda XR. I have relied on these forecasts in performing my analysis.

ii. Methodology

145. Class-wide damages resulting from Defendants' allegedly anticompetitive product-hop scheme, or Hard Switch, which was designed to force direct purchasers (including proposed Class members) to switch from Namenda IR to Namenda XR, arise from higher prices paid for branded Namenda XR than would have been paid for generic memantine hydrochloride (generic Namenda IR) in the but-for world. That is, the Hard Switch resulted in more patients switching from Namenda IR to Namenda XR between February 2014 and the present than would have been the case with a conventional product introduction (and no announced withdrawal of Namenda IR from the market). Because nearly the entire volume of Namenda IR in the market switched to generic

memantine hydrochloride following generic entry in July 2015, the vast majority of the additional Namenda IR DOT which would have occurred in the but-for world with fewer Namenda XR DOT would have likewise switched to generic memantine hydrochloride. In turn, proposed Class members would have purchased more generic memantine hydrochloride in the but-for world and would have paid less for the generic memantine they would have purchased in the but-for world than they paid for branded Namenda XR. This difference in price is the damages arising from the Hard Switch.

146. Hard Switch damages can be calculated as the difference between the actual Namenda XR price and the but-for generic memantine hydrochloride price times the difference between the actual Namenda XR DOT and but-for Namenda XR DOT multiplied by the generic penetration rate (discussed above for the pay-to-delay damages). The difference between Namenda XR DOT in the actual world and but-for world represent patients who would have been prescribed Namenda IR, many of whom would have switched to generic memantine hydrochloride in the but-for world. So, I multiplied the difference between the actual Namenda XR DOT and but-for Namenda XR DOT by the generic penetration rate in the actual world to account for the fact that some patients may want to stay on Namenda IR after the generic entry date. I used this formula to calculate damages using the NSP data for each month from July 2015 through June 2017.<sup>248</sup> I discuss the damages arising from Forest's Hard Switch below.

### iii. Calculation of But-For Prices

147. The generic memantine hydrochloride prices that occurred after the actual entry of generic memantine hydrochloride (i.e., July 2015) can be used to measure the prices proposed Class members would have paid for generic memantine hydrochloride purchased instead of brand Namenda XR. This represents an appropriate benchmark to measure the but-for prices proposed Class members would have paid for generic memantine hydrochloride. I therefore calculated average monthly generic memantine hydrochloride prices that were paid in the actual world from July 2015 to June 2017. The

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<sup>248</sup> Because I do not have the complete generic transaction-level sales data, I still rely on the NSP data to measure total market DOT, Namenda XR conversion rate, and generic penetration rate. But I can use the transaction-level data to compute the monthly average prices of Namenda IR and Namenda XR and generic memantine hydrochloride.

actual average monthly Namenda XR prices can be calculated using the NSP data or Forest's transaction-level sales data. For the purpose of calculating Hard Switch damages, I estimated the price differential between the actual average monthly prices of Namenda XR and the but-for average monthly prices of generic memantine hydrochloride from July 2015 to June 2017.

148. I discuss below a measure of the but-for Namenda XR conversion rate, which is the market share of Namenda XR<sup>249</sup> that would have occurred absent the Hard Switch. The difference between the actual and but-for Namenda XR conversion rates, multiplied by the total market DOT times the generic penetration rate, yields the amount of branded XR purchases that would have been generic Namenda IR purchases but for the Hard Switch. This volume multiplied by the difference in price between branded Namenda XR and generic Namenda IR then yields the amount of overcharges due to the Hard Switch.

#### iv. Calculation of But-For Volumes

149. For the purpose of calculating Hard Switch damages, I estimated the total volume of proposed Class members' purchases of Namenda XR that would have occurred in the but-for world absent the Hard Switch during each month from July 2015 to June 2017. That is, I multiplied the actual, total DOT for Namenda IR, Namenda XR, and generic IR purchased by proposed Class members, times the but-for conversion rate based on the analysis of Defendants' forecasts discussed below (i.e., Namenda XR's but-for market share).

150. As discussed above, evidence from internal Forest documents and testimony demonstrate that Forest studied and forecasted the effect a conventional switch (also known as a soft switch) or hard switch would have on the Namenda franchise. I relied on Forest's own documents to determine a but-for conversion rate from Namenda IR to Namenda XR that is consistent with Forest's own predictions of Namenda XR conversion absent the Hard Switch. In this section, I discuss my analysis, in which I conclude that,

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<sup>249</sup> FRX-AT-01740238-293 at 292 illustrate the formula for XR conversion rate. It defines the XR conversion rate to be "XR volume as percent to total franchise (brand and generic) volume." I have measured sales volume using DOT for this matter. See also, Forest 30(b)(6) Deposition at 48:21-23, referring to conversion from branded IR to branded XR as, "The rate at which prescriptions or market share or sales of Namenda IR would move to Namenda XR."

absent the Hard Switch, the Namenda XR conversion rate would reach 30 percent in the 18 months after Namenda XR entered the market absent the Hard Switch. In this analysis, I model the erosion rate for Namenda XR after generic entry using the experience for Namenda XR in the actual world after generics entered in July 2015. That is, I conclude that Namenda XR DOT in the but-for world would respond to the availability of lower-priced generic memantine hydrochloride in a way similar to its response in the actual world.

151. Based on my review of documents and materials in this case, I understand that Forest used various analogues of drug franchises that had experienced a conversion from an immediate release to an extended release product when forecasting the conversion rate from Namenda IR to XR. Forest updated these Namenda XR conversion forecasts regularly, sometimes creating multiple forecasts in a few weeks. A forecast document from April 2012, over a year before Namenda XR entered the market, found that “[a]nalogues support 30% peak conversion.”<sup>250</sup> Another forecast, dated nearly a year later, projected a 30 percent conversion rate for the 19 months after Namenda XR entered the market.<sup>251</sup> Forest forecasts projected a 30 percent conversion rate under a soft switch even well after Namenda XR entered the market. As shown below, Forest executives routinely referred to this as the expected conversion rate, both internally and externally.

152. For the purposes of determining the Namenda IR to XR conversion rate absent the Hard Switch, I have relied upon Forest documents forecasting the effect of a “conventional” or Soft Switch based on the actual dates of Namenda XR entry (June 2013) and Namenda IR LOE (July 2015). Using the forecast documents that were created after Namenda XR had entered the market and before the Hard Switch was implemented, I averaged the forecasted Soft Switch Namenda IR to XR conversion rate for November 2014, 18 months after Namenda XR entered the market, and found the but-for conversion rate to be approximately 30 percent. Table 3 below lists the Forest documents used to calculate the but-for conversion rate.

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<sup>250</sup> See FRX-AT-04204937.

<sup>251</sup> FRX-AT-01604399. See also, FRX-AT-00949798, FRX-AT-01688338, FRX-AT-01605826, FRX-AT-01606020, FRX-AT-01607274, FRX-AT-01605190, FRX-AT-01607267, FRX-AT-01602914, FRX-AT-01602920.

**Table 3**  
**Forest Forecast Documents with a Namenda XR entry date of June**  
**2013 and IR LOE date of July 2015**

Bates-Stamp	Document Date	Forecasted Soft Switch
		Conversion Rate at 18 months (Nov 2014)
FRX-AT-01642799	9/6/2013	24.45%
FRX-AT-01644132	9/16/2013	28.00%
FRX-AT-01617447	9/30/2013	28.00%
FRX-AT-03724325	10/4/2013	28.00%
FRX-AT-01639601	10/7/2013	28.00%
FRX-AT-03600941	10/8/2013	28.00%
FRX-AT-03769058	10/15/2013	38.00%
FRX-AT-03725539	10/29/2013	38.00%
<b>Average</b>		<b>30.06%</b>

153. In addition to creating these internal forecast documents, Forest announced in company presentations that they were expecting a 30 percent soft switch conversion rate. A presentation titled “Namenda XR Launch Plan” from January 2013 shows the “[p]rojected conversion rate[]” for Namenda XR to be 30%.<sup>252</sup> Another presentation from February 2013, titled “Namenda Franchise Business Plan” also projects the conversion rate to be 30 percent.<sup>253</sup> A May 2013 “Board of Directors Meeting” presentation also projects a conversion rate of 30 percent.<sup>254</sup> A January 2014 email to Brent Saunders, Forest’s CEO, states, “we estimate the peak conversion rate will reach 20%-30% or higher” for Namenda XR.<sup>255</sup>

154. Internal forecasts, presentations, and testimony from Forest executives indicate that the Soft Switch conversion rate was projected to reach 30 percent within the first eighteen months that XR was on the market. A December 2013 Forest presentation titled “Namenda Transition” states that the “[c]onversion rate is at 15% but on track to reach

<sup>252</sup> FRX-AT-03715033-5110 at 5042.

<sup>253</sup> FRX-AT-03852628-2730 at 2637.

<sup>254</sup> FRX-AT-01700746-778 at 773.

<sup>255</sup> FRX-AT-01876733-764 at 733.

20% - 30%”<sup>256</sup> Elaine Hochberg, then Chief Commercial Officer and Executive Vice President for Forest, stated during an October 2013 earnings call that the “future expectation on what the conversion rate could be” was in the range of 20 to 30 percent.<sup>257</sup> Six months earlier, in April 2013, Ms. Hochberg similarly stated, “We expect to convert 10% to 15% of Namenda IR in the next 12-months, and 20% to 30% in 18 to 24 months hence.”<sup>258</sup>

155. The use of 30 percent for the November 2014 conversion rate in the but-for world absent the Hard Switch is consistent with the injunction opinion of Judge Robert Sweet and company-wide Forest presentations. In his opinion, Judge Sweet found evidence that, absent the Hard Switch, Forest would have converted “approximately 30% of Namenda IR patients to Namenda XR.”<sup>259</sup>

156. Figure 9 below shows the but-for Namenda XR conversion rate based on a 30 percent but-for conversion rate at 18 months, and the actual Namenda XR conversion rate over time for the period in which we calculate damages, June 2015 through June 2017.

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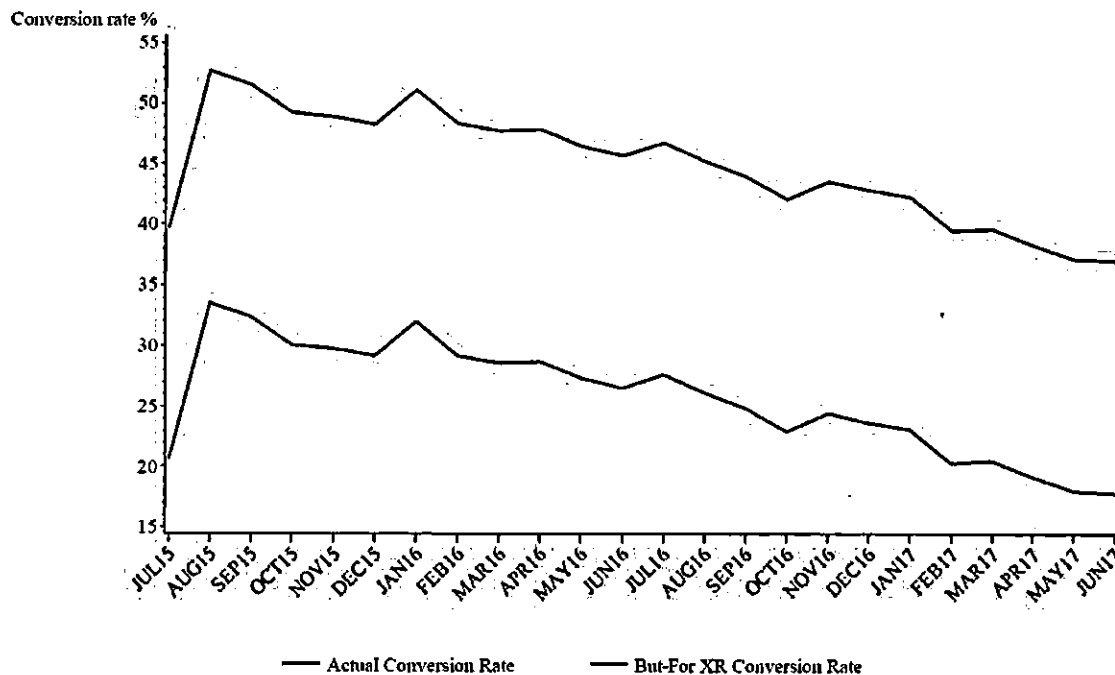
<sup>256</sup> FRX-AT-03793234-242 at 235. FRX-AT-01730731-740 at 01730735 (Namenda Franchise Business Plan September 2013, “For Namenda XR, the objective is to convert at least 30% of Namenda [IR] to Namenda XR prior to the Namenda [IR] LOE in 2015.”); FRX-AT-03769038-055 at 03769042 (October 10, 2013 Namenda XR Performance Tracker, “Namenda to Namenda XR NRX conversion rate is 16%, trending towards budget target of 30%”); FRX-AT-03726753-761 at 03726754 (December 2013 “Namenda Transition”: “[c]onversion rate is at 15% but on track to reach 20-30%.”).

<sup>257</sup> FRX-AT-01643833-851 at 843-844.

<sup>258</sup> FRX-AT-01630431-453 at 437.

<sup>259</sup> FRX-AT-01794662-4797 at 4742.

Figure 9  
Hard Switch Damages Conversion Rates



Source: NSP Data.

157. Because the actual generic entry date is July 11, 2015, I multiplied the Namenda XR DOT for July 2015 by two-thirds to account for the fact that there was no generic memantine hydrochloride available in the first ten days of the month.

v. Measurement of Damages Under the No Hard Switch But-For World

158. Using the damages methodology described above, I have estimated aggregate Hard Switch damages using the NSP data of \$814 million, as shown in Table 4 below. I can adjust this model for any given but-for conversion rate.

159. As noted above, aggregate Hard Switch damages can be calculated using either the NSP data or the transaction-level data produced in this matter. When using the transaction-level data, the only modification is that I calculated the average monthly prices of Namenda XR and generic memantine hydrochloride using the transaction-level data instead of the NSP data. The DOT of the entire market, Namenda XR conversion rate, and generic penetration rate are still calculated using the NSP data because generic

manufacturers' transaction-level data was incomplete at the time I prepared this report. As shown in Table 4 below, aggregate damages calculated using the transaction-level data are \$776 million. Using the transaction-level sales data yields similar but slightly lower damages than using the NSP data, therefore, the aggregate damages I calculated using the NSP data in Table 4 below are reliable.

**Table 4**  
**Aggregate Hard Switch Damages**  
**by Data Source**

NSP Data	Transaction-Level Data
\$814,377,824	\$775,888,693

Source: NSP data & transaction-level sales data.

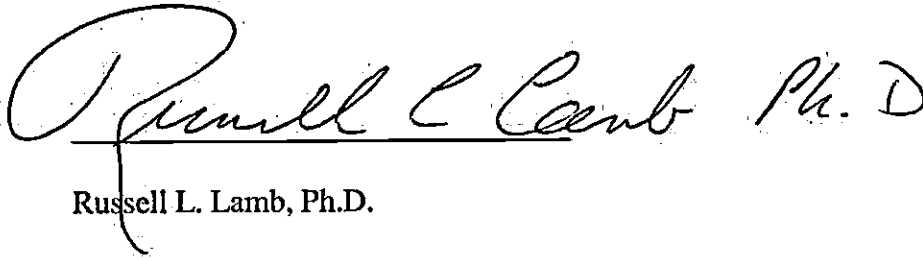
160. I have determined that damages resulting from Defendants' Hard Switch scheme are positive for each direct purchaser in the transaction-level data, which constitutes additional evidence demonstrating that all or nearly all proposed Class members who, in the actual world, purchased branded Namenda IR and Namenda XR, or just Namenda XR, were harmed by Forest's allegedly anticompetitive Hard Switch strategy, even without considering the delay in generic competition that Plaintiffs allege. I base this conclusion on my analysis of each individual customer's price and sales volume in the transaction-level data made available to me. I reserve the right to update this analysis should additional usable transaction-level data become available to me at a later stage in this litigation.

## VII. Conclusions

161. Based on the evidence and analyses presented above, as well as my training and experience in economics, I have concluded that all or nearly all proposed Class members were impacted (overcharged) by Defendants' allegedly anticompetitive conduct. I have also determined that there are formulaic methods which may be used to measure overcharge damages in the aggregate on a class-wide basis resulting from each scenario I have modeled herein. Using the methodologies described above, I have estimated total overcharge damages related to the No Reverse-Payment But-For World scenario to be



between \$6.09 billion and \$6.93 billion, and total overcharge damages related to the No Hard Switch But-For World scenario to be between \$776 million and \$814 million.

A handwritten signature in black ink that reads "Russell L. Lamb Ph.D." The signature is written in a cursive style with a large, looping initial "R".

Russell L. Lamb, Ph.D.

September 20, 2017

# Exhibit 1

## Exhibit 1a

## Total Pay-to-Delay Damages (USD) Allocated to Direct Purchasers by Market Share

## November 2012 Generic Entry

Direct Purchaser	Share of B-G Damages	Share of G-G Damages
ALBERTSONS LLC		\$158,196
AMERICAN HEALTH PACKAGING		\$203,998
AMERISOURCEBERGEN CORPORATION	\$1,564,962,697	\$1,587,460
ANDA INC	\$51,562,294	\$289,968
ASSOCIATED PHARMACIES		\$85,105
AUBURN PHARMACEUTICAL		\$69,465
BARTELL DRUGS COMPANY	\$11,988	
BELLCO DRUG CORPORATION	\$12,210,654	
BLOODWORTH WHOLESALE DRUGS		\$11,039
BURLINGTON DRUG COMPANY	\$4,186,654	\$34,154
CAPITAL WHOLESALE DRUG CO	\$236,438	\$65,314
CARDINAL HEALTH PHARMACEUTICAL	\$1,411,540,628	\$5,500,686
CVS CAREMARK		\$7,034,389
DAKOTA DRUG INC	\$20,260,941	\$84,045
DIK DRUG COMPANY	\$1,137,934	
DISCOUNT DRUG MART INC	\$872,757	\$12,269
DMS PHARMACEUTICAL GROUP	\$13,347	\$15
DROGUERIA BETANCES INC	\$14,856,014	\$153,875
DROGUERIA CENTRAL INC	\$323,780	
DROGUERIA CESAR CASTILLO	\$1,047,002	\$26
DRUGS UNLIMITED, INC.		\$11,624
EXPRESS SCRIPTS INC		\$545,482
FIRST VETERINARY SUPPLY	\$4,795	
FRANK W KERR INC	\$8,457,641	\$42,069
GENETCO INC		\$45,480
HANNAFORD BROTHERS		\$59,594
HC PHARMACY CENTRAL INC		\$179
HD SMITH LLC	\$49,975,161	\$221,060
HD SMITH WHOLESALE DRUG COMPANY	\$52,521,015	\$73,125
HE BUTT	\$57,544	\$122,757
HUMANA INC		\$363,562
INDEPENDENT PHARMACY COOPERATIVE		\$13,686
KAISER PERMANENTE		\$1,293,363
KERR DRUG INC	\$16,784	
KEYSOURCE MEDICAL, INC.		\$518,606
KROGER INC	\$60,503,974	
LOUISIANA WHOLESALE DRUG COMPANY	\$4,600,614	\$85,918
MAJOR PHARMACEUTICALS/RUGBY LABORAT		\$452,139
MASTERS PHARMACEUTICAL INC.		\$471,343
MCKESSON CORPORATION	\$2,538,437,262	\$5,695,801
MEDCO HEALTH SOLUTIONS INC		\$725,372
MEIJER INC		\$97,543
MIAMI LUKEN INC	\$2,165,547	\$15,287
MORRIS & DICKSON COMPANY LLC	\$95,096,213	\$508,007
NORTH CAROLINA MUTUAL WHOLESALE DRUG	\$24,480,457	\$117,713

**Exhibit 1a****Total Pay-to-Delay Damages (USD) Allocated to Direct Purchasers by Market Share****November 2012 Generic Entry**

Direct Purchaser	Share of B-G Damages	Share of G-G Damages
OPTUMRX INC		\$177,307
PBA HEALTH	\$2,848,128	\$38,008
PEYTONS		\$674,172
PRESCRIPTION SUPPLY INC	\$1,251,730	\$332,605
PUBLIX SUPER MARKETS INC	\$316,494	\$30,996
QUEST PHARMACEUTICALS, INC.		\$11,439
RICHIE PHARMACEUTICAL COMPANY		\$8,672
ROCHESTER DRUG COOPERATIVE INC	\$21,281,695	\$139,507
RX OUTREACH		\$4,982
SMITH DRUG COMPANY	\$87,900,247	\$466,610
SUPERVALU INC		\$35,325
TEL DRUG OF PA LLC JOANN CHRISTENS		\$44,151
THE HARVARD DRUG GROUP LLC	\$326,085	\$60,056
TOPRX LLC		\$77,214
VALLEY WHOLESALE DRUG COMPANY INC	\$878,151	\$75,185
VALUE DRUG COMPANY	\$24,200,168	\$167,459
WALMART		\$3,752,931
WINN DIXIE LOGISTICS INC		\$72,694
<b>Total</b>	<b>\$ 6,058,542,837</b>	<b>\$ 32,939,026</b>

Sources: NSP data and transaction-level data.

## Notes:

Direct Purchasers are included in the share of B-G damages if they purchased either Namenda IR or Namenda XR

Direct Purchasers are included in the share of G-G damages if they purchased generic memantine hydrochloride.

As I explain in my report, the Sun data could not be analyzed for purposes of measuring damages. Therefore, Direct Purchasers who only purchased from Sun are not included in this analysis. However, it is my opinion that they suffered antitrust injury.

## Exhibit 1b

## Total Pay-to-Delay Damages (USD) Allocated to Direct Purchasers by Market Share

## June 2012 Generic Entry

Direct Purchaser	Share of B-G Damages	Share of G-G Damages
ALBERTSONS LLC		\$158,196
AMERICAN HEALTH PACKAGING		\$203,998
AMERISOURCEBERGEN CORPORATION	\$1,732,074,709	\$1,587,460
ANDA INC	\$52,696,340	\$289,968
ASSOCIATED PHARMACIES		\$85,105
AUBURN PHARMACEUTICAL		\$69,465
BARTELL DRUGS COMPANY	\$11,990	
BELLCO DRUG CORPORATION	\$13,642,739	
BLOODWORTH WHOLESALE DRUGS		\$11,039
BURLINGTON DRUG COMPANY	\$4,638,073	\$34,154
CAPITAL WHOLESALE DRUG CO	\$266,579	\$65,314
CARDINAL HEALTH PHARMACEUTICAL	\$1,590,882,013	\$5,500,686
CVS CAREMARK		\$7,034,389
DAKOTA DRUG INC	\$22,213,805	\$84,045
DIK DRUG COMPANY	\$2,209,658	
DISCOUNT DRUG MART INC	\$1,194,208	\$12,269
DMS PHARMACEUTICAL GROUP	\$13,349	\$15
DROGUERIA BETANCES INC	\$16,771,756	\$153,875
DROGUERIA CENTRAL INC	\$543,602	
DROGUERIA CESAR CASTILLO	\$1,268,739	\$26
DRUGS UNLIMITED, INC.		\$11,624
EXPRESS SCRIPTS INC		\$545,482
FIRST VETERINARY SUPPLY	\$4,796	
FRANK W KERR INC	\$9,873,810	\$42,069
GENETCO INC		\$45,480
HANNAFORD BROTHERS		\$59,594
HC PHARMACY CENTRAL INC		\$179
HD SMITH LLC	\$49,981,929	\$221,060
HD SMITH WHOLESALE DRUG COMPANY	\$67,469,840	\$73,125
HE BUTT	\$57,552	\$122,757
HUMANA INC		\$363,562
INDEPENDENT PHARMACY COOPERATIVE		\$13,686
KAISER PERMANENTE		\$1,293,363
KERR DRUG INC	\$16,786	
KEYSOURCE MEDICAL, INC.		\$518,606
KROGER INC	\$71,632,768	
LOUISIANA WHOLESALE DRUG COMPANY	\$4,601,237	\$85,918
MAJOR PHARMACEUTICALS/RUGBY LABORAT		\$452,139
MASTERS PHARMACEUTICAL INC.		\$471,343
MCKESSON CORPORATION	\$2,855,745,727	\$5,695,801
MEDCO HEALTH SOLUTIONS INC		\$725,372
MEIJER INC		\$97,543
MIAMI LUKEN INC	\$2,388,416	\$15,287
MORRIS & DICKSON COMPANY LLC	\$106,202,815	\$508,007

**Exhibit 1b****Total Pay-to-Delay Damages (USD) Allocated to Direct Purchasers by Market Share****June 2012 Generic Entry**

Direct Purchaser	Share of B-G Damages	Share of G-G Damages
NORTH CAROLINA MUTUAL WHOLESALE DRUG	\$27,663,571	\$117,713
OPTUMRX INC		\$177,307
PBA HEALTH	\$3,213,990	\$38,008
PEYTONS		\$674,172
PRESCRIPTION SUPPLY INC	\$1,372,780	\$332,605
PUBLIX SUPER MARKETS INC	\$316,537	\$30,996
QUEST PHARMACEUTICALS, INC.		\$11,439
RICHIE PHARMACEUTICAL COMPANY		\$8,672
ROCHESTER DRUG COOPERATIVE INC	\$23,425,765	\$139,507
RX OUTREACH		\$4,982
SMITH DRUG COMPANY	\$99,549,169	\$466,610
SUPERVALU INC		\$35,325
TEL DRUG OF PA LLC JOANN CHRISTENS		\$44,151
THE HARVARD DRUG GROUP LLC	\$398,069	\$60,056
TOPRX LLC		\$77,214
VALLEY WHOLESALE DRUG COMPANY INC	\$1,038,497	\$75,185
VALUE DRUG COMPANY	\$27,483,474	\$167,459
WALMART		\$3,752,931
WINN DIXIE LOGISTICS INC		\$72,694
<b>Total</b>	<b>\$ 6,790,865,089</b>	<b>\$ 32,939,026</b>

Sources: NSP data and transaction-level data.

Notes:

Direct Purchasers are included in the share of B-G damages if they purchased either Namenda IR or Namenda XR

Direct Purchasers are included in the share of G-G damages if they purchased generic memantine hydrochloride.

As I explain in my report, the Sun data could not be analyzed for purposes of measuring damages. Therefore, Direct Purchasers who only purchased from Sun are not included in this analysis. However, it is my opinion that they suffered antitrust injury.

# Appendix A



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**Russell Lamb, Ph.D.**

**President**

**Monument Economics Group**

**Phone: (703) 615-3474**

**Email: rlamb@megconsulting.com**

**Professional Summary**

Russell Lamb is an expert in antitrust economics and has testified concerning antitrust liability, impact, and damages in U.S. District Court. He has an extensive background in applied econometrics and has developed econometric models to measure damages in a number of matters involving allegations of horizontal price fixing. He has provided expert testimony in State and Federal Courts in the United States and in Canada on a range of issues including class-certification and economic damages in antitrust, RICO and consumer fraud matters. In addition, he has provided expert advice to client attorneys at all levels of the litigation. Dr. Lamb has an extensive background in the analysis of domestic and international agricultural markets, and has authored more than 50 articles in peer-reviewed economics journals, trade press, and major newspapers.

Dr. Lamb's work has been cited by courts in certifying classes in the United States and Canada. For example, in *In re Aftermarket Automotive Lighting Products Antitrust Litigation*, the court held that his analysis provided "a sufficient basis from which to conclude that Plaintiffs would adduce common proof concerning the effect of Defendants' alleged price-fixing conspiracy on prices class members paid." In certifying the Class in *In re: Titanium Dioxide Antitrust Litigation*, the Court said, "This Court finds that Dr. Lamb's regression analysis accurately reflects the characteristics of the titanium dioxide industry, and the facts in this case." In the Canadian LCD Competition Act Class Action, the Court held that Dr. Lamb's analysis provided "evidence of a viable methodology for the determination of loss on a class-wide basis." In *In re: Puerto Rican Cabotage Litigation*, the



Court held that "Dr. Lamb [had] set forth a reputable and workable model for determining damages as to individual class members." In certifying the class in *Clarke and Rebecca Wixon, et al. v. Wyndham Resort Development Corp., et al.*, the Court held that "Dr. Lamb [had] presented a plausible class-wide method of proof." In certifying the class in *Eugene Allan, et al. v. Realcomp II, Ltd., et al.*, the Court held that "the Plaintiffs have produced sufficient evidence that common proofs will yield a finding of class-wide damages that predominates over any specific individualized damages. The Lamb Report and Lamb Reply are sufficient to establish this fact." Furthermore, Dr. Lamb was the Indirect Purchaser Plaintiffs' expert in the *In re: Polyurethane Foam Antitrust Litigation* matter, which was certified by the Court in April 2014.

With regard to agricultural economics, Dr. Lamb has a particular expertise in agricultural markets and has undertaken extensive original research and econometric analysis on markets for agricultural commodities. His articles on agricultural economics have been published in peer-reviewed journals, trade press, and major newspapers. Dr. Lamb regularly presents at conferences on topics including the state of the U.S. Economy and farm policy.

Prior to rejoining Nathan Associates, Dr. Lamb established the Arlington, VA office of Advanced Analytical Consulting Group where he served as a Principal, as well as the Washington, DC office of Econ One where he served as Managing Director and DC Office Head. In these positions, he developed and managed a practice of ten litigation professionals. He earlier served as an Assistant Professor of Agricultural Economics and faculty member of the Graduate Group in Economics at North Carolina State University and as an Economist and Senior Economist in the Federal Reserve System of the United States, at the Federal Reserve Board and the Federal Reserve Bank of Kansas City.

#### Education

- Ph.D., Economics, University of Pennsylvania, 1994
- M.A., Economics, The University of Maryland, 1989
- B.A., Economics, The University Tennessee, 1987

Expert Testimony Offered

**2017** *In Re Capacitors Antitrust Litigation*

- United States District Court Northern District of California San Francisco Division
- Case No. 3:14-CV-03264-JD
- Expert Declaration, February 24, 2017
- Expert Reply Declaration, April 28, 2017
- Testified at deposition, May 17, 2017
- Opinion concerning class certification issues regarding indirect purchasers
- Retained by Cotchett, Pitre & McCarthy, LLP

**2016** *Deere Construction, LLC, v. Cemex Construction Materials Florida, LLC, et al.*

- United States District Court Southern District of Florida
- Case No. 15-24375-CIV-ALTONAGA/O'Sullivan
- Expert Report, September 14, 2016
- Testified at deposition, September 27, 2016
- Opinion concerning class certification issues
- Retained by Kozyak Tropin & Throckmorton, LLP; Harke Clasby & Bushman, LLP; and McCallum, Methvin & Terrell, P.C.

*Luke Begonja v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2015-CA-010943)*  
*Gerrit Brouwer, Jr., et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2014-CA-008533)*  
*Gary Gottschalk, et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2015-CA-001957)*  
*Susan Hatzipetro, et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2014-CA-007996)*  
*Shelly Keegan, et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2015-CA-001953)*  
*Yvonne Klebba, et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2014-CA-008535)*  
*Adriane McConville, et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2015-CA-001960)*  
*Ernest W. Yeager Jr., et al. v. Wyndham Vacation Resorts, Inc., et al. (Case No. 2014-CA-008054)*

- In the Circuit Court of the Ninth Judicial Circuit in and for Orange County, Florida
- Expert Report, September 14, 2016
- Testified at deposition, October 27-28, 2016
- Testified at deposition, March 2-3, 2017
- Expert Report, May 19, 2017
- Testified at deposition, August 29, 2017
- Opinion concerning damages issues
- Retained by Badham & Buck, LLC

*In Re: Evanston Northwestern Healthcare Corporation Antitrust Litigation*

- United States District Court for the Northern District of Illinois Eastern Division
- No. 07-C-4446
- Expert Report, July 28, 2016
- Expert Reply Report, January 25, 2017
- Testified at deposition, September 20, 2016
- Testified at deposition, February 22, 2017
- Opinion concerning damages issues

- Retained by Miller Law LLC

*In Re: Ductile Iron Pipe Fittings ("DIPF") Direct Purchaser Antitrust Litigation*

- United States District Court for the District of New Jersey
- Civ. No. 12-711 (AET)(LHG)
- Declaration, May 27, 2016
- Reply Declaration, March 31, 2017
- Testified at deposition, July 8, 2016
- Opinion concerning class certification, merits, and damages issues
- Retained by Cohen Milstein Sellers & Toll PLLC and Kaplan Fox & Kilsheimer LLP

*Nestlé Purina Petcare Company v. Blue Buffalo Company, Ltd.*  
*Blue Buffalo Company, Ltd. v. Nestlé Purina Petcare Company, et al.*  
*Blue Buffalo Company, Ltd. v. Wilbur-Ellis Company, et al.*  
*Diversified Ingredients, Inc. v. Wilbur-Ellis Company, et al.*  
*Diversified Ingredients, Inc. v. Custom AG Commodities, LLC, et al.*

- United States District Court for the Eastern District of Missouri Eastern Division
- Cause No.: 4:14-CV-00859 RWS
- Affidavit, March 17, 2016
- Opinion concerning pricing issues
- Retained by Lashly & Baer, P.C.

*In Re: Cast Iron Soil Pipe and Fittings Antitrust Litigation*

- United States District Court Eastern District of Tennessee at Chattanooga
- Case No.: 1:14-md-2508
- Declaration, March 4, 2016
- Testified at deposition, May 19, 2016
- Opinion concerning class certification and damages issues
- Retained by Cohen Milstein Sellers & Toll PLLC, Cera LLP, and Kaplan Fox & Kilsheimer LLP

*Darren Ewert v. Denso Corporation, et al.*

- Supreme Court of British Columbia
- Case No. S-135610
- Expert Report, February 12, 2016
- Expert Reply Report, January 5, 2017
- Opinion concerning class certification issues
- Retained by Camp Fiorante Matthews Mogerman

*Serge Asselin v. Hitachi, LTD & al.*

- Cour Supérieure Disctirct de Québec
- Case No. 200-06-000180-144
- Expert Report, February 11, 2016

- Opinion concerning class certification issues
- Retained by Siskinds LLP

**2015** *Thomas Mervyn v. Atlas Van Lines, Inc., et al.*

- United States District Court Northern District of Illinois Eastern Division
- Case No. 1:13-CV-03587
- Expert Declaration, September 3, 2015
- Expert Report, February 4, 2016
- Opinion concerning data issues
- Opinion concerning damages issues
- Retained by Miller Law LLC

*Thomas Mervyn v. Nelson Westerberg, Inc.*

- United States District Court Northern District of Illinois Eastern Division
- Case No. 1:11-CV-06594
- Expert Report, July 27, 2015
- Opinion concerning damages issues
- Retained by Miller Law LLC

*Lane's Gifts and Collectibles, LLC v. Microsoft Online, Inc.*

- United States District Court Western District of Washington at Seattle
- No. 2:12-cv-01181-BJR
- Expert Report, March 23, 2015
- Testified at deposition, May 21, 2015
- Opinion concerning damages issues
- Retained by Nix, Patterson & Roach, L.L.P. and Kessler Topaz Meltzer & Check, LLP

*BlueCross BlueShield of Tennessee, Inc., et al. v. King Pharmaceuticals, Inc., et al.*

- In the Circuit Court for Cocke County, Tennessee
- Civil Action No. 32941-II
- Expert Report, January 23, 2015
- Opinion concerning impact and damages issues
- Retained by Miller Law LLC

*In Re: Domestic Drywall Antitrust Litigation*

- United States District Court for the Eastern District of Pennsylvania
- MDL No. 2437 13-MD-2437
- Trial Expert Report, January 23, 2015
- Reply Expert Report, April 23, 2015
- Expert Report concerning class certification, August 3, 2016
- Expert Reply Report concerning class certification, January 9, 2017
- Testified at deposition, February 25, 2015
- Testified at deposition, August 30, 2016

- Testified at deposition, February 17, 2017
- Testified at class certification hearing, April 27, 2017
- Expert Supplemental Report, July 31, 2017
- Opinion concerning merits issues regarding direct purchasers
- Opinion concerning class certification issues, impact and damages regarding direct purchasers
- Retained by Cohen Milstein Sellers & Toll PLLC, Berger & Montague, P.C., and Spector Roseman Kodroff & Willis, P.C.

*In Re: Processed Egg Products Antitrust Litigation*

- United States District Court for the Eastern District of Pennsylvania
- MDL No. 2002
- Expert Declaration, January 22, 2015
- Expert Reply Declaration, April 3, 2015
- Testified at deposition, May 7, 2015
- Opinion concerning merits and damages issues regarding indirect purchasers
- Retained by Straus & Boies, LLP

**2014** *In Re: Class 8 Transmission Indirect Purchaser Antitrust Litigation*

- United States District Court for the District of Delaware
- Civil Action No. 11-cv-00009 (SLR)
- Declaration, November 3, 2014
- Reply Declaration, March 6, 2015
- Trial Declaration, March 27, 2015
- Trial Reply Declaration, July 2, 2015
- Testified at deposition, December 17, 2014
- Testified at deposition, March 16, 2015
- Testified at class certification hearing, March 25, 2015
- Testified at deposition, May 1, 2015
- Opinion concerning class certification issues regarding indirect purchasers
- Opinion concerning merits and damages issues regarding indirect purchasers
- Retained by Glancy Binkow & Goldberg LLP

*Mark S. Wallach, et al., v. Eaton Corporation, et al.*

- United States District Court District of Delaware
- Civil Action No. 10-260-SLR
- Expert Report, November 3, 2014
- Expert Reply Report, March 6, 2015
- Trial Expert Report, March 27, 2015
- Trial Expert Reply Report, July 2, 2015
- Testified at deposition, December 16, 2014
- Testified at deposition, March 16, 2015
- Testified at class certification hearing, March 25, 2015
- Testified at deposition, May 1, 2015
- Opinion concerning class certification issues regarding direct purchasers

- Opinion concerning merits and damages issues regarding direct purchasers
- Retained by Cohen Milstein Sellers & Toll PLLC

*Sheridan Chevrolet Cadillac Ltd., et al., v. Furukawa Electric Co. Ltd., et al.*  
Ontario Superior Court of Justice  
Court File No. CV-12-446737-00CP

*Sheridan Chevrolet Cadillac Ltd., et al., v. Mitsubishi Electric Corporation, et al.*  
Ontario Superior Court of Justice  
Court File No. CV-14-496994-00CP

- Expert Report, April 15, 2016
- Expert Report, October 14, 2014
- Opinion concerning class certification issues
- Retained by Siskinds LLP

*Resco Products, Inc., v. Bosai Minerals Group Co., Ltd., et al.*

- United States District Court for the Western District of Pennsylvania
- Civil Action No.: 2:06-cv-325-JFC
- Expert Report, September 24, 2008
- Expert Report, September 29, 2014
- Supplemental Expert Report, December 15, 2014
- Testified at deposition, February 13, 2015
- Opinion concerning damages
- Retained by Boies, Schiller & Flexner LLP

*Fond Du Lac Bumper Exchange Inc., et al. v. Jui Li Enterprise Company Ltd. et al.*

- United States District Court Eastern District of Wisconsin
- Case No.: 2:09-cv-00852-LA
- Affidavit, August 1, 2014
- Affidavit, November 4, 2014
- Declaration, April 24, 2015
- Expert Report, July 15, 2015
- Expert Reply Report, November 24, 2015
- Expert Surreply Report, January 15, 2016
- Expert Trial Report, August 18, 2016
- Expert Trial Reply Report, December 20, 2016
- Testified at deposition, October 1, 2015
- Testified at deposition, February 13, 2017
- Opinion concerning class certification and damages issues
- Opinion concerning Defendants' replacement data
- Opinion concerning Defendant and LKQ transaction-level data
- Opinion concerning merits and damages issues
- Retained by Stueve Siegel Hanson, LLP

*Meredith Corporation, et al., v. SESAC, LLC, et al.*

- United States District Court for the Southern District of New York
- 09 Civ. 9177 (PAE)
- Expert Report, July 10, 2014
- Opinion concerning class certification issues
- Retained by Weil, Gotshal & Manges LLP

*Janet Skold, et al., v. Intel Corporation, et al.*

- Superior Court of the State of California for the County of Santa Clara
- Case No. 1-05-CV-039231
- Expert Report, June 14, 2007
- Testified at deposition, August 31, 2007
- Testified at deposition, January 10, 2014
- Opinion concerning class certification issues
- Opinion concerning damages issues
- Retained by Girard Gibbs LLP

*In Re: Polyurethane Foam Antitrust Litigation*

- United States District Court Northern District of Ohio Western Division
- MDL No. 2196
- Declaration, June 11, 2013
- Reply Declaration, October 23, 2013
- Trial Declaration, March 18, 2014
- Reply Trial Declaration, June 30, 2014
- Testified at deposition, August 20, 2013
- Testified at deposition, November 20, 2013
- Testified at class certification hearing, January 15, 2014
- Testified at deposition, April 14, 2014
- Testified at deposition, July 14, 2014
- Opinion concerning class certification issues regarding indirect purchasers
- Opinion concerning merits and damages issues
- Retained by Miller Law LLC

Professional Experience

Economic Consulting Positions

**Monument Economics Group**, October 11, 2016 - Present

**Nathan Associates, Inc.**, Arlington, VA, *Senior Vice President*, January 2013 – September 20, 2016

**Advanced Analytical Consulting Group, Inc.**, Washington DC area, *Principal*, March 2011 – January 2013

**Econ One Research, Inc.**, Washington, DC, *Managing Director and D.C. Office Head*, July 2006 March 2011

- Opened and staffed the DC office; managed office affairs on a daily basis

- Retained as an expert witness for damages and class certification issues in antitrust, breach of contract, product liability and RICO cases; representative testimony includes determination of liability and damages in a case involving resale price maintenance in consumer products, class certification in a horizontal price-fixing case involving international travel in the airline industry, class certification in a consumer class action involving RICO claims in state court
- Industry pre-litigation analyses for consumer products, chemicals, and other industries

**Navigant Consulting, Inc.**, Washington, DC, *Associate Director*, February 2006 – July 2006

- Case manager for damages analysis in asbestos litigation and personal injury claims

**Nathan Associates, Inc.**, Arlington, VA, *Managing Economist*, July 2004 – February 2006

- Case manager for economic analysis of class certification and damages issues in antitrust and RICO cases involving the chemical, consumer products and tobacco industries
- Retained as expert on damages for direct purchasers of NBR in the Crompton Global Settlement; submitted an Affidavit on damages and appeared before the Special Master for the Crompton Global Settlement (the Hon. Kenneth Feinberg)

#### **Board Membership**

- Board of Advisors, American Antitrust Institute, Washington, DC
- Department of Economics Advisory Council, University of Tennessee, Knoxville, *Chairman*, Spring 2006 – April 2011

#### **Teaching Positions**

- The George Washington University, Washington, DC, *Adjunct Assistant Professor of Economics*, Fall 2004 – present
- North Carolina State University (NCSU), *Assistant Professor* (Department of Agricultural and Resource Economics), Fall 1999 – Spring 2004
- The University of Pennsylvania, *Adjunct Instructor*, Summer 1990 – Spring 1994

#### **Additional Teaching Experience**

- The Wharton School Evening Division, Philadelphia, PA, summer 1993
- Rutgers University, Camden, NJ, summer 1993
- Philadelphia College of Textiles and Science, Philadelphia, PA, fall 1992
- The Pennsylvania State University, Media, PA, 1991
- St. Mary's College of Maryland, St. Mary's City, MD, summer 1989
- The University of Maryland University College, College Park, MD, 1988-1989

#### **Courses Taught**



- Managerial Economics for MBA students (George Washington University)
- Law and Economics (George Washington University)
- Intermediate Microeconomics – graduate level (George Washington University)
- Latin American Economic Development (George Washington University)
- International Trade: Theory and Policy (George Washington University)
- International Finance: Theory and Policy (George Washington University)
- Agricultural Production and Supply – Ph.D. field course (North Carolina State University)
- U.S. Agricultural Policy (North Carolina State University)
- Microfinance: Theory, Practice and Regulation (Superintendencia de Banca y Seguros)
- Statistical Analysis for Economics (University of Pennsylvania)
- Principles of Microeconomics (University of Maryland, St. Mary's College of Maryland)
- Principles of Macroeconomics (University of Pennsylvania, The Wharton School, Penn State University)
- Fundamentals of Micro/Macro Economics (University of Maryland)
- Environmental and Natural Resource Economics (Rutgers)

#### **Federal Reserve Experience**

Federal Reserve Bank of Kansas City, *Senior Economist* (Jan. 1998 – Aug. 1999), *Economist* (Jan. – Dec. 1997)

- Analysis of regional, macroeconomic developments in agriculture, and energy
- Research on public policy towards agriculture in the U.S., especially the impact of farm policy reform
- Briefings to the Bank president and outside groups on the regional economy, agriculture, agricultural trade

Board of Governors of the Federal Reserve System, *Economist*, **June 1994 – Dec. 1996**

- Analysis of macroeconomic conditions, commodity markets and prices (CPI, PPI, Core prices)
- Forecasting of agricultural output, prices, and income
- Briefings to the Board of Governors on agriculture and food-price developments

#### **Other Consulting Experience**

World Perspectives, Inc., 2003 - 2004

- Analysis of trade barriers for U.S. exports of feed ingredients, pet food ingredients, and food ingredients
- Analysis of the impact of a Free Trade Area of the Americas on U.S. soybean producers

- Analysis of the potential for U.S. Halal-certified meat exports to the Middle East  
Womble Carlyle Sandridge & Rice, LLP, 2003 - 2004
- Provided expert testimony related to the estimation of business profitability  
Smith-Moore, 2002 - 2003
- Provided economic analysis of the U.S. Tobacco Program  
Superintendencia de Banca y Seguros (Lima, Peru), 1998 - 2000
- Developed and taught a class on Microfinance issues (in English) to students enrolled in a training program for bank examiners; the program was sponsored by the Inter-American Development Bank.  
World Bank, Africa Technical Department, 1992 - 1993
- Summarized and provided an overview of data available on African economic and social indicators  
ACG-Afrique, January 1993
- Provided critical review of a study document outlining the impact of structural adjustment on African agriculture

#### Professional Organizations

- National Association for Business Economics
- American Economic Association

#### Papers, Publications and Speeches

##### **Papers Published in Refereed Journals**

- "Government Regulation and Quality in the U.S. Beef Market," (with Peyton Ferrier) *Food Policy*, 32:1 (2006) pp. 84-97
- "Rent-seeking in U.S.-Mexican Avocado Trade," *Cato Journal*, 26:1 (Winter 2006) pp. 159-177
- "Consolidation in U.S. Agriculture and the Role of Public Policy," *The ICFAI Journal of Agricultural Economics*, 1(2004) pp. 7-16
- "Fertilizer Use, Risk, and Off-farm Labor Markets in the Semi-Arid Tropics of India," *American Journal of Agricultural Economics*, 85(2) (May 2003) pp 359-371
- "Inverse Productivity: Land Quality, Labor Markets, and Measurement Error," *Journal of Development Economics*, 71 (2003) pp. 71-95
- "A Market-Forces Policy for the New Farm Economy?" *Review of Agricultural Economics*, 24 (2002) 15-30
- "Food Crops, Exports, and the Short-run Policy Response of Agriculture in Africa," *Agricultural Economics*, 22 (2000) 271-298

- "FAIR Act Implications for Land Values in the Corn Belt," (with Jason Henderson) *Review of Agricultural Economics*, 22 (2000) 102-119
- "Why are Estimates of Agricultural Supply Response So Variable?" (with Francis X. Diebold) *Journal of Econometrics*, 76 (1997) 367-373

**Non-refereed Publications, Articles and Editorials**

- "The Predominance Requirement for Antitrust Class Actions – Can Relevant Market Analysis Help?" (with Jeffrey Leitzinger) American Bar Association – Section of Antitrust Law, *Economics Committee Newsletter*, Spring 2007, pp. 17-22
- "Reform of U.S. Farm Policy in an Integrating World Economy," forthcoming in *Developing Countries in the WTO System*, published by Rowman & Littlefield, 2006
- "New Farm Economy," *Regulation*, Winter 2003-2004, Washington, DC: Cato Institute for Public Policy Research (2003)
- "What Road Will U.S. Economy Take in 2003?" *Southeast Farm Press*, February 5, 2003
- "Fast Track for the Tax Cuts," guest editorial, *News and Observer* (Raleigh, NC), January 18, 2003
- "The 2002 Farm Bill," (with Blake Brown and Michele Marra) *NC State Economist*, November/December 2002
- "Economy-minded Tax Cuts: Bush's Reductions Provided the Boost to Lift U.S. From Recession," guest editorial, *News and Observer* (Raleigh, NC), July 2, 2002
- "Policy Only Effective if Farm Economy is Recognized," special report to *Feedstuffs*, June 5, 2000
- "Aid During Crisis of Little Long-term Help to Farmers," guest editorial, *Kansas City Star*, August 23, 1999
- "Survey of Agricultural Credit Conditions," Federal Reserve Bank of Kansas City, *Regional Economic Digest*, various issues, 1997-1999
- "U.S. Agriculture at the Crossroads in 1999," *Economic Review*, Federal Reserve Bank of Kansas City, 84 (1999)
- "Can U.S. Oil Production Survive the 20th Century?" *Economic Review*, Federal Reserve Bank of Kansas City, 84 (1999)
- "Will the Tenth District Catch the Asian Flu?" (with Ricardo Gazel) *Economic Review*, Federal Reserve Bank of Kansas City, 83 (1998)
- "From the Plains to the Plate: Can the Beef Industry Regain Market Share?" (with Michelle Beshear) *Economic Review*, Federal Reserve Bank of Kansas City, 83 (1998)
- "U.S. Agriculture: Another Solid Year in 1998?" (with Mark Drabenstott) *Economic Review*, Federal Reserve Bank of Kansas City, 83 (1998)
- "How Will the 1996 Farm Bill Affect the Outlook for District Farmland Values?" *Economic Review*, Federal Reserve Bank of Kansas City, 82 (1997).

- "Food Prices and the Farm Sector," monthly *Greenbook* (various issues, 1994-1996), Federal Reserve Board of Governors, Washington, DC
- "Hedge to Arrive Contracts," Memo to the Board of Governors, Federal Reserve Board of Governors, Washington, DC, June 5, 1996
- "Prices in the May Greenbook," Federal Reserve Board of Governors, Washington, DC, May 19, 1996
- "Prices in the March Greenbook," Federal Reserve Board of Governors, Washington, DC, March 24, 1996
- "Commodity Price Developments," Weekly memo to the Board of Governors, Federal Reserve Board of Governors, Washington, DC, August 1994 – December 1996

#### Conference Presentations

- "Class Action Developments," panelist at the American Antitrust Institute's 6<sup>th</sup> Annual Private Antitrust Enforcement Conference, Washington, DC, December 4, 2012
- "Consequences for Antitrust Thought and Practice," presented at the American Antitrust Institute Invitational Symposium: Antitrust Challenge of Multi-Channel Distribution in the Internet Age, Washington, DC, June 22, 2011
- "The U.S. Economy in the Year Ahead," presented at the Long Company Annual Conference, Chicago, IL, September 11, 2009 and September 19, 2008
- "The U.S. Economic Outlook," presented at the Industry Outlook Conference, Chicago, IL, October 17, 2006 and October 18, 2005
- "How Will the Economy Impact Your Business?" presented at the Long Company Annual Conference, Las Vegas, NV, August 14, 2004
- "Focus on The Economy" presented at *Milling and Baking News* annual Purchasing Managers' Conference, Kansas City, MO, June 14, 2004, June 10, 2003 and June 11, 2002
- "The U.S. Economic Outlook and Agriculture," presented at the Industry Outlook Conference, Chicago, IL, October, 2003
- "The U.S. Economic Outlook and Agriculture," presented at the Industry Outlook Conference, Breckenridge, CO, April 7, 2002
- "The U.S. Economic Outlook: The Cost of Terror," presented at the Southern Agricultural Outlook Conference, Atlanta, GA, September 24, 2001
- "The Economy in Focus," presented at *Milling and Baking News* annual purchasing managers' conference, Kansas City, MO, June 5, 2001
- "The Great American Growth Machine," presented at the Southern Agricultural Outlook Conference, Atlanta GA, September 27, 2000
- "The Economy in Focus," presented at *Milling and Baking News* annual purchasing managers' conference, Kansas City, MO, June 6, 2000
- "The Outlook for the U.S. Pork Sector," presented to the Industry Outlook Conference, Las Vegas, NV, April 17, 2000

- "The National Economic Outlook: The Road Ahead," presented to the Food Industry Outlook Conference, Breckenridge, CO, April 11, 1999
- "Farm Policy for the New Millennium," presented to Federal Reserve Bank of Kansas City, Division of Bank Supervision and Regulation, Bank Examiners' Annual Training Conference, January 7, 1999
- "The Impact of the 1996 Farm Bill on Farmland Values," (with Jason Henderson) first place poster presentation at the annual meetings of the American Agricultural Economics Association, Salt Lake City, August 4, 1998
- "A Note on the Inverse Productivity Relationship," presented at the annual meetings of the Western Economic Association International, Seattle, July 1997
- "Off-farm Labor Supply and Fertilizer Use in the Semi-Arid Tropics of India," presented at the annual meetings of the American Agricultural Economics Association, August 1995
- "Prices for Food-Away-From-Home and Core Inflation: Some Empirical Relationships," (with James E. Kennedy) presented at the Federal Reserve System Committee on Agriculture, Richmond, VA, October 1995
- "Some Simple Dynamics of Farming," presented at the annual meetings of the American Agricultural Economics Association, Orlando, August 1993
- "Structural Adjustment and Food Security," (with W. Graeme Donovan), presented at the annual meetings of the American Agricultural Economics Association, Orlando, August 1993
- "Structural Adjustment and African Agricultural Supply Response to Exchange Rate and Price Movements," (with W. Graeme Donovan), presented at the annual meetings of the Southern Agricultural Economics Association, Tulsa, January 1993

#### **Other Presentations**

- Panelist, "Antitrust Class Actions – Where Are We? A 360 Degree Perspective," NYSBA Annual Antitrust Law Section Meeting," January 30, 2014
- Panelist, Retrospective on the Baby Products Litigation, ABA Section of Antitrust Law: Pricing Conduct Committee, July 31, 2013
- Panelist, Economic Forecasting Summit, Northern Indiana Workforce Investment Board, Inc., March 29, 2007
- "The Welfare Benefits of USDA Beef Quality Certification Programs" (with Peyton Ferrier), presentation memo, 2007
- "Reform of U.S. Farm Policy in an Integrating World Economy," presented to the Cordell Hull Institute, Trade Policy Roundtable on Reform of U.S. Farm Policy and the WTO System, Washington, DC, March 31, 2006
- "The Case for a Market-forces Farm Policy in the U.S." presented at the Cordell Hull Institute Trade Policy Roundtable, Washington DC, May 26, 2005

- "How Will the Economy Impact Your Business?" presented at the Apple Processors Association annual meeting, Homewood Resort, June 20, 2004
- "The U.S. and International Economic Outlook," presented at the AgFirst Loan Officer's Seminar, Atlanta, GA, October 30-31, 2002
- "Will the U.S. Economy Bounce or Crawl?" presented to the Eastern Bankruptcy Institute, North Myrtle Beach, SC, June 1, 2002
- "The U.S. Economic Outlook and Agriculture," presented to the National Pork Producers Pork Action Group, Washington, DC, April 10, 2002
- "The U.S. Economic Outlook" presented to the Risk Management Associates, Raleigh, NC, February 7, 2002
- "The U.S. Economic Outlook: The Cost of Terror," presented at the National Pork Producers Pork Action Group, Marco Island, FL, November 14, 2001
- "Consolidation in Agriculture and the Role of Public Policy," paper presented to the Southern Extension Meetings, Williamsburg, VA, June 13, 2000
- "The New Farm Economy," presented at the annual meetings of the National Association of County Agricultural Agents, Omaha, NE, September 14, 1999
- "Regional Economic Update," presented to bankers in Kansas, Nebraska, Missouri, and Oklahoma as part of the Regulatory Update Seminar, Federal Reserve Bank of Kansas City, April 1999
- "The National Economic Outlook," presented to Oklahoma State University Advanced Cattle Management Seminar, Stillwater, OK, March 11, 1999
- "Regional Economic Update," presented to Thomas Hoenig, President, Federal Reserve Bank of Kansas City, November 13, 1998
- "Can the Tenth District Survive the Asian Flu?" The Federal Reserve Bank of Kansas City Economic Forums, nine presentations to bankers in Wyoming, Oklahoma, and New Mexico, September 21 - October 21, 1998
- "The Impact of Asian Economic Developments on Tenth District Agriculture," presented to Thomas Hoenig, President, Federal Reserve Bank of Kansas City, January 30, 1998
- "The Outlook for the Nebraska Economy," The Federal Reserve Bank of Kansas City: Nebraska Economic Forums, six presentations to bankers in Nebraska, October 6 - 15, 1997
- "Update on the Macroeconomy and Special Briefing on Forecast Performance at the Kansas City Fed," presented to Thomas Hoenig, President, Federal Reserve Bank of Kansas City, August 13, 1997
- "Regional Economic Update," presented to Thomas Hoenig, President, Federal Reserve Bank of Kansas City, May 14, 1997 and March 21, 1997
- "Producer Prices, Retail Sales, and Agricultural Commodity Markets," presented to the Board of Governors of the Federal Reserve System, July 15, 1996

Referee Experience

Referee for the following academic journals:

- World Development, 1993
- Journal of Development Economics, 1994, 1995
- International Economic Review, 1995
- Journal of Human Resources, 1997
- Journal of Business and Economics Statistics, 1997
- American Journal of Agricultural Economics, 1999, 2001, 2002
- Agricultural Economics, 2000, 2001, 2004
- Agricultural Finance Review, 2000, 2004
- Review of Agricultural Economics, 2000, 2002, 2004
- Journal of Agricultural and Resource Economics, 2000, 2001, 2002
- Emerging Markets Review, 2001
- Contemporary Economic Policy, 2004

Fellowships, Honors and Awards

**Fellowships**

- Departmental Fellowship, University of Pennsylvania, 1989-1990
- Dean's Fellowship, University of Pennsylvania, 1991-1992
- Graduate School Fellowship, University of Maryland, College Park, 1987-1989

**Honor Societies and Professional Organizations**

- Phi Eta Sigma National Honor Society
- Mortar Board National Honor Society
- Golden Key National Honor Society
- Vice President for Professional Activities, Delta Sigma Pi

**Awards**

- Top Graduate in Liberal Arts, University of Tennessee, Knoxville, Spring 1987
- Chancellor's Citation for Extraordinary Professional Promise, University of Tennessee, Knoxville
- Chancellor's Citation for Outstanding Academic Achievement, University of Tennessee, Knoxville
- First place poster presentation, American Agricultural Economics Association annual meetings, August 1998 (with Jason Henderson)
- Honorable mention, American Agricultural Economics Association, Essay for the 21st Century, 2001, "A Market Forces Policy for the New Farm Economy"



- Honorable mention, American Antitrust Institute Antitrust Enforcement Awards, Outstanding Antitrust Litigation Achievement in Economics (for work on In Re Titanium Dioxide Antitrust Litigation matter)

**External Funding**

- “Unmanufactured Flue-Cured Tobacco Exports and the Export Component of the Quota Formula.” \$13,890 NC Tobacco Foundation. With Blake Brown 2000/2001.

**Professional Activities and Services**

**Graduate Student Advising**

M.A. degree, North Carolina State University

- Joe Weinberg (Political Science)

Master of Economics, North Carolina State University

- William Pole (2000)
- Dwight Wilder (Chairman, 2002)
- Adrian Atkeson (2002)
- Sarah Spivey
- Li Zhang (Chairman, 2003)
- Nia Atmadja (2003)

Doctor of Philosophy, North Carolina State University

- William Deese (2003)
- Peyton Ferrier (Chairman, 2004)
- Yang Wang (2003)
- Bobby Huggett (2003)
- Syed Wadood (Chairman, 2004)
- Henry Kuo

**Economic and Statistical Modeling Skills**

- Experience with all major statistical software including SAS, STATA, LIMDEP and C++; applied econometric modeling skills in damage analysis of consumer industries, chemicals industries, and agricultural markets, correlation analysis for class certification.



# Appendix B

## Materials Considered

### Pleadings and Legal Correspondence

In the United States District Court for the Southern District of New York, *J M Smith Corporation d/b/a, Smith Drug Company v. Actavis, PLC, Forest Laboratories, LLC, Merz GmbH & Co. KGAA, Merz Pharma GmbH & Co. KGAA and Merz Pharmaceuticals GmbH*, Civil Action No. 15-cv-7488, First Amended Class Action Complaint, October 13, 2015.

Ontario Superior Court of Justice, Fanshawe College of Applied Arts and Technology and LG Phillips LCD Co., 54054CP

United States District Court District Of Maryland, *In re: Titanium Dioxide Antitrust Litigation*, 10-cv-0318 (RDB), 2013

United States District Court District of Puerto Rico, *In re: Puerto Rican Cabotage Antitrust Litigation* MDL 1960, 3:08-md-01960, 2011

United States District Court Eastern District of Wisconsin, *Fond du Lac Bumper Exchange Inc. et al v. Jui Li Enterprise Company Ltd. et al.*, 2:09-cv-00852, 2016

United States District Court for the District of Columbia, *Federal Trade Commission, Plaintiff, v. Whole Foods Market, Inc., and Wile Oats Markets, Inc., Defendants*, Civil Action No. 1:07-cv-01021-PLF, Plaintiff Federal Trade Commission's Corrected Brief on Its Motion for Preliminary Injunction, August 1, 2007

United States District Court Northern District of Ohio, *In re: Polyurethane Foam Antitrust Litigation*, 1:10-md-02196, 2016

United States District Court of Delaware, *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD., Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH, Plaintiffs, v. Cobalt Laboratories Inc., Lupin Pharmaceuticals, Inc., Lupin Ltd., Orchid Pharmaceuticals Inc., Orchid Chemicals & Pharmaceuticals Ltd. (d/b/a Orchid Healthcare), Teva Pharmaceuticals USA, Inc., Upsher-Smith Laboratories, Inc., Wockhardt USA Inc., and Wockhardt Limited, Defendants*, Complaint, filed January 10, 2008

United States District Court of Delaware, *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD., Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH, Plaintiffs, v. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc., Defendants*, Complaint, filed January 10, 2008.

United States District Court of Delaware, *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD., Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH, Plaintiffs, v. Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Limited, Genpharm Inc., Genpharm, L.P., Interpharm Holdings, Inc., Interpharm Inc., Mylan Pharmaceuticals Inc., Ranbaxy Inc., Ranbaxy Laboratories Limited, Kendle International Inc., and Sun India Pharmaceutical Industries Limited (a/k/a Sun Pharmaceuticals Industries Limited), Defendants*, Complaint, filed January 25, 2008.

United States District Court Southern District of New York, *In Re Namenda Direct Purchaser Antitrust Litigation*, Memorandum Decision and Order Granting in Part and Denying in Part Plaintiffs' Motion for Collateral Estoppel and Partial Summary Judgment on Count One; Denying Plaintiffs' and Defendants' Motions for Partial Summary Judgment on Count Five, May 23, 2017.

*United States v. Brown Shoe Co.*, 370 U.S. 294 (1962).

**Depositions and Declarations**

30(b)(6) Deposition of Mark Devlin, dated August 29, 2017  
 William Meury Investigational Hearing, July 10, 2014

**Bates-Stamped Materials**Documents

FRX-AT-00348814-16	FRX-AT-01621655	FRX-AT-01747389
FRX-AT-00949798	FRX-AT-01626869	FRX-AT-01747623-634
FRX-AT-00950357-58	FRX-AT-01630431-453	FRX-AT-01749967-970
FRX-AT-00953209-252	FRX-AT-01639601	FRX-AT-01750160-0219
FRX-AT-00956973-75	FRX-AT-01639601	FRX-AT-01750245-48
FRX-AT-01592880	FRX-AT-01641155	FRX-AT-01750895-51082
FRX-AT-01593279-282	FRX-AT-01641216	FRX-AT-01751083-1263
FRX-AT-01595333	FRX-AT-01642799	FRX-AT-01751482-1646
FRX-AT-01595850	FRX-AT-01643833-851	FRX-AT-01751858
FRX-AT-01595859	FRX-AT-01644132	FRX-AT-01752159
FRX-AT-01601379	FRX-AT-01646209	FRX-AT-01752159
FRX-AT-01602903	FRX-AT-01649318	FRX-AT-01774559
FRX-AT-01602914	FRX-AT-01649808	FRX-AT-01775151-161
FRX-AT-01602920	FRX-AT-01651403	FRX-AT-01775214-17
FRX-AT-01602965	FRX-AT-01652322	FRX-AT-01775240-41
FRX-AT-01604015	FRX-AT-01652323-29	FRX-AT-01775242
FRX-AT-01604019	FRX-AT-01655656	FRX-AT-01775264-5301
FRX-AT-01604141	FRX-AT-01657073	FRX-AT-01775302-319
FRX-AT-01604399	FRX-AT-01670083	FRX-AT-01775327-28
FRX-AT-01605190	FRX-AT-01671038	FRX-AT-01775329-330
FRX-AT-01605826	FRX-AT-01671042	FRX-AT-01775500-518
FRX-AT-01606020	FRX-AT-01671046	FRX-AT-01779417-19
FRX-AT-01606118-134	FRX-AT-01671049	FRX-AT-01780565-66
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FRX-AT-01607267	FRX-AT-01686075	FRX-AT-01781368-381
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FRX-AT-01607876	FRX-AT-01696384-6411	FRX-AT-01783493-95
FRX-AT-01608854	FRX-AT-01700746-778	FRX-AT-01783541-596
FRX-AT-01609615	FRX-AT-01711279	FRX-AT-01794622-797
FRX-AT-01609806	FRX-AT-01720912	FRX-AT-01794662-4797
FRX-AT-01612936	FRX-AT-01726785-792	FRX-AT-01806018
FRX-AT-01612936	FRX-AT-01730505-0664	FRX-AT-01819478-481
FRX-AT-01614455-56	FRX-AT-01730731-740	FRX-AT-01821687-89
FRX-AT-01614461-62	FRX-AT-01731390-1541	FRX-AT-01828875-892
FRX-AT-01614463-64	FRX-AT-01734091-4148	FRX-AT-01829171-73
FRX-AT-01614465-66	FRX-AT-01740238-293	FRX-AT-01874319
FRX-AT-01616631	FRX-AT-01743198-3250	FRX-AT-01876733-764
FRX-AT-01617447	FRX-AT-01743320-21	FRX-AT-01893031-041
FRX-AT-01621653-54	FRX-AT-01746793-6804	FRX-AT-01893676-78

FRX-AT-03169232-273	FRX-AT-03724325	FRX-AT-03910305-311
FRX-AT-03169392-9423	FRX-AT-03724798	FRX-AT-03910390
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FRX-AT-03169456-478	FRX-AT-03726753-761	FRX-AT-03982972-75
FRX-AT-03487982-999	FRX-AT-03732735-742	FRX-AT-04008540-42FRX-
FRX-AT-03490110-131	FRX-AT-03745356-58	AT-04038657-58
FRX-AT-03490173-0243	FRX-AT-03768540	FRX-AT-04051660-62
FRX-AT-03490463	FRX-AT-03769038-055	FRX-AT-04056749-751
FRX-AT-03496434-449	FRX-AT-03769058	FRX-AT-04063453
FRX-AT-03565770-73	FRX-AT-03769058	FRX-AT-04204937
FRX-AT-03573080-82	FRX-AT-03793234-242	FRX-AT-04217620-22
FRX-AT-03587816-18	FRX-AT-03793759-765	FRX-AT-04225926-28
FRX-AT-03600530	FRX-AT-03793847-856	FRX-AT-04254209-228
FRX-AT-03600941	FRX-AT-03807249-250	FRX-AT-04283678-79
FRX-AT-03600941	FRX-AT-03807370-71	FRX-AT-04312274-281
FRX-AT-03624221-254	FRX-AT-03813904-05	FRX-AT-04363541-48
FRX-AT-03671360-64	FRX-AT-03835462-5510	FRX-AT-04369600-613
FRX-AT-03684464-66	FRX-AT-03838093	FRX-AT-04380946-47
FRX-AT-03684533-35	FRX-AT-0384961FRX-AT-	FRX-AT-04518688-690
FRX-AT-03686632-33	03852628-2730	FRX-AT-04519466-67
FRX-AT-03713353-54	FRX-AT-03860760	FRX-AT-04536177-6202
FRX-AT-03715033-5110	FRX-AT-03861621-658	FRX-AT-04544984-45011
FRX-AT-03716706	FRX-AT-03863755	FRX-AT-04568337-345
FRX-AT-03718466-491	FRX-AT-03863958-992	FRX-AT-04599903-917
FRX-AT-03724244-47	FRX-AT-03866054-063	MYLMEMA_000023-26
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DRL (Namenda AT Litig)0001798	Memantine report
DRL (Namenda AT Litig)0003686	MYLMEMA_000001 - MYLMEMA_000002
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FRX-AT-04406019 - FRX-AT-04406051	Info BY QUARTER
FRX-AT-04524046	TEVANIR-00003877 - TEVANIR-00003878
FRX-AT-04532864 - FRX-AT-04532868	
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Anneal Pharmaceuticals of New York, LLC provided data answers on July 25, 2017  
 Dr. Reddy's Laboratories, Inc. provided data answers on June 12, 2017  
 Forest Laboratories, Inc. provided data answers on August 1, 2017  
 Lupin Pharmaceuticals, Inc. provided data answers on June 26, 2017  
 Mylan Pharmaceuticals, Inc. provided data answers on June 9, 2017  
 Sun India Pharmaceuticals Industries Limited provided data answers on August 23, 2017

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IMS Institute for Healthcare Informatics, "HSRN Data Brief: National Sales Perspectives," IMS Health, 2011

"Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," Prepared for the Kaiser Family Foundation by: The Health Strategies Consultancy LLC, March 2005.

#### Press Releases

CVS Health Corporation, "CVS Health and Omnicare Sign Definitive Agreement for CVS Health to Acquire Omnicare," May 21, 2015. Available at <https://cvshealth.com/newsroom/press-releases/cvs-health-and-omnicare-sign-definitive-agreement-cvs-health-acquire-omnicare>.

Forest Laboratories Inc., "Forest Obtains Six Months U.S. Pediatric Exclusivity for NAMENDA® and NAMENDA XR®," *BusinessWire*, June 18, 2014. Available at <http://www.businesswire.com/news/home/20140618005438/en/Forest-Obtains-Months-U.S.-Pediatric-Exclusivity-NAMENDA%C2%AE>.

Forest Laboratories, Inc., "Forest Announces U.S. Availability of New Once-Daily NAMENDA XR," *BusinessWire*, June 13, 2013. Available at <http://www.businesswire.com/news/home/20130613005088/en/Forest-Announces-U.S.-Availability-New-Once-Daily-NAMENDA>.

Forest Laboratories, Inc., "Forest Laboratories to Discontinue NAMENDA® Tablets, Focus on Once-Daily NAMENDA XR®," *BusinessWire*, February 14, 2014. Available at <http://www.businesswire.com/news/home/20140214005829/en/Forest-Laboratories-Discontinue-NAMENDA%C2%AE-Tablets-Focus-Once-Daily>.

#### Government Agency Publications

"How is Alzheimer's Disease Treated?" National Institute on Aging, updated August 2, 2017. Available at <https://www.nia.nih.gov/health/how-alzheimers-disease-treated>.

Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998.

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U.S. Department of Justice and the Federal Trade Commission, "Horizontal Merger Guidelines," August 19, 2010.

U.S. Food and Drug Administration, "FDA Approves Expanded Use of Treatment for Patients With Severe Alzheimer's Disease," October 13, 2006.

#### News Articles

“Orchid Chem settles litigation with Forest Labs,” *Reuters*, April 29, 2010

Ben James, “Forest, Merz, Wrap Up Namenda Patent Litigation,” *Law360*, July 22, 2010

Melissa Lipman, “Lupin Gets Namenda License In Forest Settlement,” *Law360*, December 22, 2009

Shannon Henson, “Upsher-Smith, Others Exit Namenda Patent Case,” *Law360*, September 14, 2009

#### Websites

Drugs@FDA, “ANDA 079225.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=079225>.

Drugs@FDA, “ANDA 090041.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090041>.

Drugs@FDA, “ANDA 090043.” Available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090043>.

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